UK NEQAS
Haematology and Transfusion

UK NEQAS Haematology

Annual Report to Participants
January – December 2016

April 2017

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Contents

Executive Summary

Welcome to the UK NEQAS Haematology Annual Report to participants, covering the period January to December 2016. This report has been adapted from the report submitted to the National Quality Assurance Advisory Panel for Haematology for the same period and all information covers that time period, unless otherwise stated.

If you have any questions on the content of the report, please contact me directly either by email (barbara.delasalle@whht.nhs.uk) or telephone (01923 217878).

All data included in the report cover the period January – December 2016 unless otherwise stated.

Premises and environment
The Scheme is co-located with UK NEQAS Blood Transfusion Laboratory Practice (BTLP) at Watford General Hospital. On behalf of the Scheme and the UK NEQAS charity host, we acknowledge the active support of our host and operating organisation, the West Herts Hospitals NHS Trust.

Personnel
The Scheme scientific team was fully staffed throughout 2016. Paul McTaggart will retire in April 2017 after 26 years' with UK NEQAS and Yvonne John has been appointed as UK NEQAS Haematology Service Manager in his place.

Organisation and Quality Management.
The West Herts Hospitals NHS Trust operating UK NEQAS Haematology and Transfusion (UKAS accredited centre 7805) had a surveiilance visit by UKAS in August 2016. There were four non-conformances found, all of which were cleared to schedule. The UK NEQAS Haematology ESR scheme was added to the scope of the accreditation and is now fully accredited.

The UK NEQAS FMH scheme was integrated fully into the UK NEQAS BTLP scheme from April 2016, from its former basis of shared operation with UK NEQAS Haematology.

The Quality Manager will change in 2017 from Clare Milkins to Claire Whitham, on Clare Milkins' retirement.

The National Quality Assurance Advisory Panel reviewed the operation of UK NEQAS Haematology in 2016 and concluded that it was operating satisfactorily (note the only options are satisfactory/unsatisfactory).

Steering Committee and Scientific Advisory Groups

UK NEQAS Haematology is dependent upon the input of the members of the Steering Committee and Scientific Advisory Groups (SAGs), who contribute their time and expertise to the improvement of UK NEQAS (H) services to participants. The chair of the Steering Committee is Dr Kate Ryan and the Deputy Chair is Dr Wayne Thomas. New members were recruited to the Steering Committee and Scientific Advisory Groups in 2016 and details of Steering Committee members are available from the Scheme office and website. We thank all our advisors for their support and welcome new expressions of interest from participants interested in working with the Scheme.

Scheme Operation
Participant laboratory numbers increased by 6.5% in the year to December 2016 and the total number of participant registrations increased to just over 5,000. Membership of the Digital Morphology CPD scheme increased by 1.1% to just over 3,000.

Professor Barbara Bain, Dr Chris McNamara and Dr John Parker-Williams have provided expert comment on the Blood Films reports during 2016 and will be joined in 2017 by Dr Mike Leach. Professor Peter Chiodini has provided expert comment on the Malaria RDT reports. Dr John Old and Dr Cornelis Harteveld have formed an expert panel for the performance assessment of the DNA Haemoglobinopathies surveys.

The Scheme continues to supply 6 month overall summary reports on participant performance in Abnormal Haemoglobins, Newborn Sickle Screening and DNA for Diagnostics in the Haemoglobinopathies to the NHS Sickle and Thalassaemia Screening Programme.

Scheme Design
The NRBC scheme continued to operate on a pilot basis and will do so for 2017. Prospective changes in commercial material may allow NRBC counting to be integrated into the ADLC scheme.

Cumulative performance scoring using the UK NEQAS scoring model has been introduced for the ESR and the Plasma Viscosity schemes. The major work item in scoring has been the development of performance scoring for Blood Films for Morphology, which is now at the point of testing with volunteer laboratories. Participants in all schemes are contacted directly in the case of errors in performance.

Various changes to instrument grouping have been made in the automated counting schemes.

Equipment, IT and materials

A new, bespoke bottling machine was delivered in December 2016 and is being validated for use.

The Newborn Sickle screening (NH) scheme became fully web operated. The Cytochemistry (CY) scheme will complete transfer to web entry in 2017 (just reports outstanding). The Plasma Viscosity (PV) and ESR (ES) schemes transferred to web operation in 2016 and an in-house system for automated reports is in development for the DNA Haemoglobinopathies (DN) scheme.

Survey material is a key area of concern to the Scheme and the provision of cellular survey material to support EQA at clinically significant analyte levels, in a format that resembles patient specimens, remains a major challenge. A key area for improvement is the quality of bone marrow slides for haemosiderin staining.

Morphology Champions 2016

I would like to take this opportunity to thank those participants who have supported the Scheme with the provision of cases for Blood Films for Morphology. The active support of these Morphology Champions is greatly appreciated and contributes significantly to the range of cases we provide. This support comes from the general culture of the laboratory and also individual proactive scientists and clinicians looking out for cases to refer to us. Thank you to all concerned!

In 2016, the following hospitals provided one or more cases for use in the Blood Films scheme and their contribution and support is very much appreciated:

- Queen Elizabeth Hospital– Woolwich
- Royal Berkshire Hospital – Reading
- Watford General Hospital
- Central Middlesex Hospital, London
- Northwick Park Hospital, Harrow
- Royal Marsden Hospital – Sutton
- Queen's Hospital, Romford
- St Mary's Hospital, Paddington
- St George's Hospital, Tooting
- Whipps Cross Hospital, London
- Charing Cross Hospital, London
- Hammersmith Hospital, London
- St John's Hospital, West Lothian

Meetings and communications

The Scheme held the 19th Annual Participants' Symposium for over 250 delegates in Manchester and has contributed to other meetings and significant external organisations, presenting a number of posters.

The Scheme has contributed to the WHO EQA manual, a chapter in Dacie and Lewis and several peer reviewed papers.

The Scheme Annual Report to participants and the Participants' Manual (current version 7) is available on-line for download. The Manual was sent to participants in hard copy in 2016.

The Scheme is represented on a number of influential external committees.

Barbara De la Salle, Scheme Director
April 2017

April 2016

Contact Details

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Background and Overview

Headline responsibilities

Work area	Lead staff
Governance and transparency	Director
External project collaboration	Director
Implementation of IT system/website development	IT Manager
ISO 17043 accreditation	Quality Manager
IEQAS/WHO collaboration	IEQAS Coordinator
Staffing	Director
Succession/contingency planning	Director
Scheme profile/publicity	Director
Participant liaison	Business Manager
Participants' meeting management	Executive Assistant
Manufacturers' contact	Data Manager
Competition	Director/Business Manager
Morphology SAG coordination	Morphology Lead
General SAG coordination	Automated Counting Lead
Special SAG coordination	Haemoglobinopathy Specialist

Staffing

The current scheme establishment is listed below. All were full time unless stated otherwise.

Scheme Director – Barbara De la Salle
Service Manager –Yvonne John (from 30.1.17)
Morphology Lead –Jon Sims
Automated Counting Lead –Vatsala Soni
Haemoglobinopathy Specialist Consultant – Dr Barbara Wild (0.6 WTE)
EQA Scientist – Nikki Emodi
EQA Scientist – Zeno Abid (0.8 WTE)
Assistant Practitioner – Gulala Karim
Assistant Practitioner – Paula Dynes
Medical Laboratory Assistant – James Hindell

Other administrative, logistics and IT staff are employed jointly with UK NEQAS BTLP.

Key shared posts are:

Quality Manager – Claire Whitham
IT Manager – Vasilis Rapanakis
Business Manager – Nazia Hussain
Office Manager – Mayuri Wadhia
Executive Assistant – Isabella De-Rosa

IT and website

Transfer to web based or electronic operation continued in 2016. The uptake of web operation is over 95%, where this facility is available. The Plasma Viscosity and ESR schemes were transferred to web operation in 2016, electronic reports are now available for manual white blood cell differential counting and DNA for Haemoglobinopathies reports are returned by email in pdf format.

The Cytochemistry scheme will be transferred to full web operation from the second distribution of 2017; leaving the remaining schemes to be transferred as the RDT Malaria, Blood Component Quality Monitoring and the Liquid Newborn option in the Abnormal Haemoglobins scheme.

All registration and re-registration documents are now distributed electronically and facilities are available for participants to make changes to their registered contact details on-line.

Representation on External Committees

The Scheme Director and other staff are members of a number of external, national and international committees, including the Laboratory Subgroup and the Independent Quality Assurance Review Group for the National Sickle and Thalassaemia Screening Programme, the UK Proficiency Testing Group, the BSH Guidelines General Haematology Task Force, the ICSH, the EuroBloodNet European Reference Network and the European Quality Assurance in Laboratory Medicine (EQALM) organisation.

Steering Committee

The Steering Committee Chair is Dr Kate Ryan and the Vice-Chair is Dr Wayne Thomas. A full list of Steering Committee and SAG members is available from the Scheme office and the contact details for key Steering Committee members is available to download from www.ukneqash.org.

General Haematology Scientific Advisory Group Report (Automated Counting)

Mr Ian Mellors chairs the group and Mr Alun Roderick is the vice-chair. Mr John Lambert, Mr Graham Bellamy and Mr Stephen Garner joined the group; Dr Rod Hinchliffe and Mr Brendan Fitzpatrick left. The expert assessors are Mr Ian Mellors (FBC and Automated Differential Count), Dr John Ardern (FBC and Automated Differential Count), Mr Alun Roderick (Reticulocyte Count), Dr Wayne Thomas (Plasma Viscosity and ESR), Mr Andy Weir (Plasma Viscosity and ESR), Mr Stephen Garner (Component Monitoring).

A full schedule of distributions was made for the **FB, ADLC, RE and CM automated counting schemes, the ESR and PV schemes and the Pilot scheme for NRBC.**

The PV and ESR schemes have been transferred to on-line operation and cumulative scoring implemented for both. The ESR scheme was submitted as an extension to our scope of accreditation by UKAS and this was approved.

2 **NRBC pilot** exercises were issued using commercial survey material in 2016. No material was available for Beckman Coulter instruments, therefore only Sysmex X-Class analysers were included. The survey material is currently under review to explore the feasibility of amalgamating automated NRBC counting in the ADLC scheme.

The changes to instrument groupings made in 2016 were:

- Coulter T Series and Horiba Instruments groups were suspended as the number of instruments registered in each group fell to fewer than 20. The remaining participants were transferred to the all methods group for performance monitoring
- The Scheme monitored the grouping of the Sysmex XN instruments in FBC, which are currently grouped with other X class instruments. The need to separate the two instrument types was not evident

A questionnaire on the laboratory diagnosis of anaemia was developed and distributed in collaboration with colleagues in NHSBT as part of a wider NHSBT research project.

The Scheme met with representatives of all the major instrument manufacturers in 2016, to review new developments, performance grouping, instrument specific information given to participants and other issues of joint interest.

Special Haematology Scientific Advisory Group Report (Haemoglobinopathies and Red Cell Enzymopathies)

Dr Barbara Wild chairs the group. Dr Gavin Cho and Mr David Hawden joined the group; Mr Martin Jarvis and Dr Gail Miflin left the group. The expert assessors are Mr Jason Eyre (Abnormal Haemoglobins), Ms Sarah Brown (Newborn Sickle Screening) and Dr Steve Keeney (DNA for Haemoglobinipathies). Mr David Hawden will become the expert assessor for the G6PD scheme.

A full schedule of distributions of the Abnormal Haemoglobins (AH), Newborn Sickle Screening (NH), DNA Diagnostics for Haemoglobinopathies (DN) and Red Cell Enzymes (G6PD) schemes was made.

The **Abnormal Haemoglobins (AH)** scheme made 2 distributions of Hb C carrier blood in 2016 in addition to Hb S carriers. Six distributions of the simulated liquid newborn samples have been made, each with 2 specimens per distribution.

The number of participants in the **Newborn Sickle Screening (NH)** scheme remain steady at approximately 30. The scheme transferred to full electronic operation in 2016. Further work has been undertaken to optimise the dried blood spot specimens for tandem mass spectrometry, with testing undertaken at 2 sites.

One sample was withdrawn from distribution in the **DNA Diagnostics for Haemoglobinopathies (DN)** scheme in 2016. An additional specimen will be sent in the survey in early 2017 to make up the expected numbers of samples for participants. Although every participant has received a summary report and the 'model answer' for each case distributed, there has been a delay in returning the personalised, scored reports, due to sickness and a redesign of the report format. This was rectified in early 2017 and reporting is now up-to-date. Survey material has been provided from cases surplus to diagnostic testing, although the scheme continues to gather cases for storage as cell lines.

A proposal for a new guideline on the laboratory diagnosis of **G6PD deficiency** has been approved by the BSH Guidelines committee and a writing group established. The group will draw on information from the G6PD patterns of practice questionnaire distributed in 2015/2016, which is reported in a later section of this report.

The Scheme Director made 6-monthly reports to the National Sickle and Thalassaemia Screening Programme on participant performance. Where requested by the Sickle and Thalassaemia Programme, the Scheme Director discloses the identity of any laboratory providing antenatal or neonatal haemoglobinopathy screening services in England, where permission is granted by the laboratory.

Morphology Scientific Advisory Group Report (Blood Films, Malaria RDT, Cytochemistry, Digital Morphology)

The group is chaired by Dr John Burthem. Mr John Lambert joined the group. The expert assessors are Dr John Burthem (Blood Films for Morphology), Michelle Brereton (Blood Films for Morphology), Professor Peter Chiodini (Blood Films for Parasites and Rapid Diagnostic Testing for malaria), Dr John Parker-Williams (Cytochemistry) and Nora Kinsella (Digital Morphology).

The panel of expert morphology advisors, who provide expert commentaries for the Blood Films and Cytochemistry schemes, includes Professor Barbara Bain, Dr John Parker-Williams, Dr Chris McNamara and Dr Mike Leach.

UK NEQAS Haematology continues to work closely with UK NEQAS for Parasitology for the provision of Blood Films for Parasite Identification and specimens for Malaria Rapid Diagnostic Testing.

The quality of data returned for the **Manual Differential** exercises remains a cause for concern, despite some small improvements. The data entry screen has been amended to prevent some of the 'rubbish' data being submitted and the report will be updated to provide graphical representation of the data returned.

The development of performance scoring in **the Blood Films for Morphology and the Cytochemistry** schemes has been undertaken on a shadow basis and is being testing with a panel of volunteer laboratories.

The numbers of participants in **SBB (CY)** continues to fall and is approximately 25. The scheme will be monitored for long term viability. The MSAG noted the poor quality of many of the bone marrow cases used for **Haemosiderin (CY)**. Most are haemo-diluted and lack any particles. Trial commercial marrow slides were no better, neither were bone marrow harvest slides. The next option will be bone marrow from animal sources with possible digital images of cases for clinical interpretation.

The **Digital Morphology CPD** scheme continues to maintain and increase membership. The current software platform will no longer be supported from the end of 2018 and UK NEQAS Haematology is working with an alternative supplier to develop a new platform.

WHO Collaborating Centre for Quality Assurance in Haematology

All IEQAS Haematology distributions and reports went out to schedule in 2016, coordinated by Vatsala Soni. The annual collaborating centre report was submitted to schedule and accepted by the WHO. The centre has been awarded an approval for performance of work (APW) to undertake an evaluation of a rapid diagnostic testing kit for G6PD activity in under-resourced healthcare regions by the WHO.

Accreditation Status

ISO17043 Accreditation

The West Herts Hospitals NHS Trust operating UK NEQAS Haematology and Transfusion had a surveillance visit by UKAS against ISO17043 in August 2016. Four non-conformances were noted, all were cleared to schedule. The ESR scheme was added to the scope of accreditation in January 2017.

UK NEQAS Haematology currently holds accreditation for the following schemes:

- Full Blood Count
- Automated Differential Leucocyte Count
- Reticulocyte Count
- Blood Component Quality Monitoring
- Plasma Viscosity
- ESR
- Blood Films for Morphology, Parasite Identification and Manual Differential
- Cytochemistry (Haemosiderin and SBB)
- Malaria Rapid Diagnostic Testing
- Abnormal Haemoglobins, including the Emergency Sickle Screening (SS) and Liquid Newborn Screening (LN) options
- Newborn Sickle Screening
- DNA for Diagnostics in the Haemoglobinopathies
- Red cell enzymes

The following schemes are not part of the current accreditation scope:

- NRBC pilot
- Digital Morphology for CPD

Audit of Performance Targets January to December 2016

The Scheme has assessed performance for the period January – December 2016 against the performance established within the quality management system.

Distribution of survey specimens to schedule: 100% target achieved.

Physical integrity of specimens: The target was achieved for all surveys distributed.

Packing errors: These remain low, with 94.5% (102/108) distributions achieving the ≤0.5% of specimen sets notified to us as incorrectly packed (target ≥90%). 48/42,323 specimen sets (0.1%, compared to 0.4% in 2015) overall were reported were replaced as a result of packing errors

Specimen quality: The targets for specimen quality were achieved for all specimen pools except for bone marrow slides distributed for cytochemistry. However, most participants reported results on these specimens, even where they reported them as unsatisfactory.

Feedback to participants: Turnaround times for reports are now set for each scheme and published to participants in an annual schedule. The target is to issue 90% of reports electronically within one day of the date published in the schedule. When reviewed by quarter, the achievement rate was 56% in quarter 1, 79% in quarter 2 and 86% in both quarters 3 and 4.

Complaints: there is no target for the number of complaints but all should receive an acknowledgement within one week and 70% should be fully dealt with within 4 weeks. 100% of complaints were fully dealt with within the performance targets.

Performance monitoring: Targets listed in the quality manual are for 80% of persistent unsatisfactory performance (PUP) letters or outlier (UP) results to be notified to the consultant contact for UK participants within 10 working days of the report being issued. In 2016, performance letters for 86% of the distributions eligible for performance assessment were distributed within the target time period.

EQA performance: The scheme is registered with the College of American Pathologists proficiency testing programme for relevant surveys (FBC, Automated differential count, Reticulocyte count, ESR, Blood film morphology, Blood parasites, Haemoglobinopathies and G6PD) and participates in all UK NEQAS surveys under PRN 20028. There has been no out-of-consensus performance in either CAP or UK NEQAS.

Scheme participants and workload

Registered participants

The number of registered participants increased in 2016 (6.5% increase). The overall number of participations by scheme increased by 3.0% from 4,899 to 5,048 with another 3,021 individual participants in digital morphology (1.1% increase in 2016).

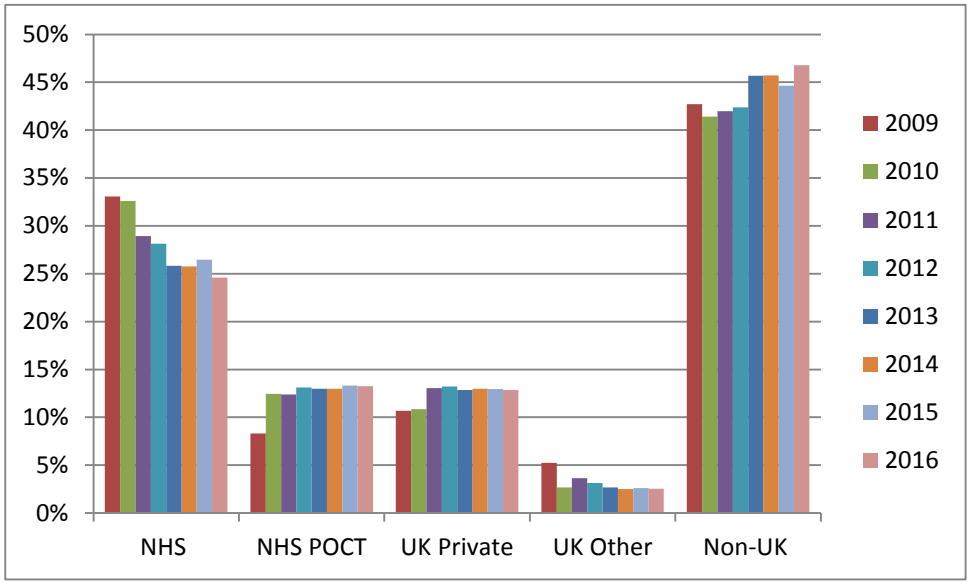
Non-UK participants formed 47% of the participants registered and 32% of the total registrations.

The scheme continued to work with commercial and charitable organisations to provide bespoke interlaboratory assessment schemes for clinical trials and other work.

Participation by Laboratory Type 2010 - 2016

	2016	2015	2014	2013	2012	2011	2010
NHS laboratories	360	364	359	358	358	364	366
NHS POCT	194	183	181	180	172	156	140
UK Private labs	188	178	181	178	176	164	122
UK Other laboratories	37	36	35	37	43	46	30
Non-UK laboratories	685	614	637	633	543	528	465
TOTAL	**1464**	**1375**	**1393**	**1386**	**1292**	**1258**	**1123**

Proportions of different participant laboratory types (2009-2016)



Participation by survey type at December 2016

Scheme	UK	Non-UK	Total
FB	694	380	1074
HB	113	27	140
CM	12	15	27
DL	659	300	959
RE	277	176	453
NR	124	17	141
ES	280	50	330
PV	44	4	48
AH	147	190	337
SS	131	33	164
NH	22	4	26
LN	28	6	39
DN	10	37	47
G6	126	107	233
BF/PA	331	198	529
HS	152	18	170
SB	20	9	29
RD	250	52	302
TOTAL	**3420**	**1623**	**5048**

Key:

FB	Full Blood Count
HB	FB (Hb only option)
CM	Blood Component Quality Pilot
DL	ADLC
RE	Reticulocyte Count
NR	NRBC Pilot
ES	ESR
PV	Plasma Viscosity
AH	Abnormal Haemoglobins (Full)
SS	AH (Sickle Screening only)
LN	AH (Liquid Newborn option)
NH	Newborn Sickle Screening
DN	DNA Diagnostics
G6	Red Cell Enzymes (G6PD)
BF/PA	Blood Films for Morphology, Parasite Identification and Manual Differential
HS	Cytochemistry (Haemosiderin)
SB	Cytochemistry (Sudan Black B)
RD	Malaria Rapid Diagnostics

Note that the General Haematology Scheme also provided services to 3021 individual practitioners registered in the Digital Morphology CPD scheme in 2016.

Surveys distributed

Twelve consolidated survey distributions were made during the year with other smaller distributions of specialist and pilot schemes. Each consolidated distribution contained Full Blood Count specimens with different combinations of other surveys:

- Full Blood Count: 12 distributions *per annum*
- ADLC, Retic counting, Abnormal Haemoglobins (AH and SS options), G6PD: 6 distributions *per annum*
- ESR: 4 distributions *per annum*
- Manual differential count, Cytochemistry, Blood Films for Parasite Identification, RDT Malaria: 4 distributions *per annum*
- Blood Films for Morphology: 8 distributions *per annum*

The following surveys were distributed separately from the main distribution in 2016:

- POCT Hb only option of FBC: 12 distributions *per annum*
- Newborn sickle screening scheme: 12 distributions *per annum*
- Plasma viscosity scheme: 12 distributions *per annum*
- Blood component monitoring scheme: 4 distributions *per annum*
- DNA Diagnostics for Haemoglobinopathies: 3 distributions *per annum*
- Liquid newborn (LN) specimen option in the Abnormal Haemoglobins scheme: 6 distributions *per annum*
- NRBC pilot scheme: 2 distributions *per annum*
- Digital Morphology CPD: 6 exercises *per annum*

For each survey and pilot scheme, the specimens distributed during the year and results returned are listed in the appropriate sections of this report.

Full Blood Count (FB)

List of analytes

WBC (10^9/L)
Hb (g/L)
RBC (10^{12}/L)
PCV (L/L)
MCV (fL)
MCH (pg)
MCHC (g/L)
Platelets (10^9/L)

The scheme includes a Hb only option for point of care testing instruments.

Registration for Full Blood count

	Laboratories		Systems	
	Total	**UK**	**Total**	**UK**
December 2015	1057	691	2148	1353
December 2016	1074	694	2229	1376

Registration for Hb only option

	Laboratories		Systems	
	Total	**UK**	**Total**	**UK**
December 2015	134	110	391	307
December 2016	140	113	431	331

Analysers registration by group (excluding miscellaneous)

Instrument Group	**December 2016**		**December 2015**	
	Total	**UK**	**Total**	**UK**
Beckman Coulter UniCell DxH 800	201	137	175	126
Cell-Dyn 3200 & Ruby	29	3	33	5
Cell-Dyn 4000 & Sapphire	43	12	44	8
Coulter LH Series	93	35	138	58
Coulter T Series	~	~	18	1
Diaspect Medical	32	7	24	0
HemoCue B-Hemoglobin	349	317	330	300
HemoCue Hb 301	21	1	18	1
Horiba Instruments	~	~	28	19
Horiba Pentra Series	126	72	122	73
Siemens ADVIA 120	258	156	280	157
Sysmex K Series	45	23	44	25
Sysmex pocH-100i	357	319	342	304
Sysmex X-Class	755	457	613	413
Sysmex XT Series	237	143	239	149

Changes to instrument groupings during the year:

- Coulter T Series and Horiba Instruments groups were suspended as the number of instruments registered in each group fell to fewer than 20. The remaining participants were transferred to the all methods group for performance monitoring.

Specimens distributed

The scheme provided and distributed a balanced spread of samples in 2016 that provided proficiency testing challenges to laboratories in clinical decision making areas for, WBC's, Haemoglobin, RBC's and platelets.

Two specimens of partially fixed human whole blood were included in each of the twelve FB surveys distributed. Two specimens of unfixed, CPD anticoagulated, human whole blood were included in each of the 12 Hb only option distributions sent.

The range of all methods means for the main analytes that have been included for scoring in Full Blood Count was:

Parameter		Jan – Dec 2016	Jan – Dec 2015
Hb	**(g/L)**	67.8 – 183.3	78 – 192
RBC	**(10^{12}/L)**	2.29 – 6.23	2.71 – 6.35
WBC	**(10^{9}/L)**	0.9 – 18.45	0.85 – 22.16
Platelets	**(10^{9}/L)**	11.3 – 954	13.2 - 822

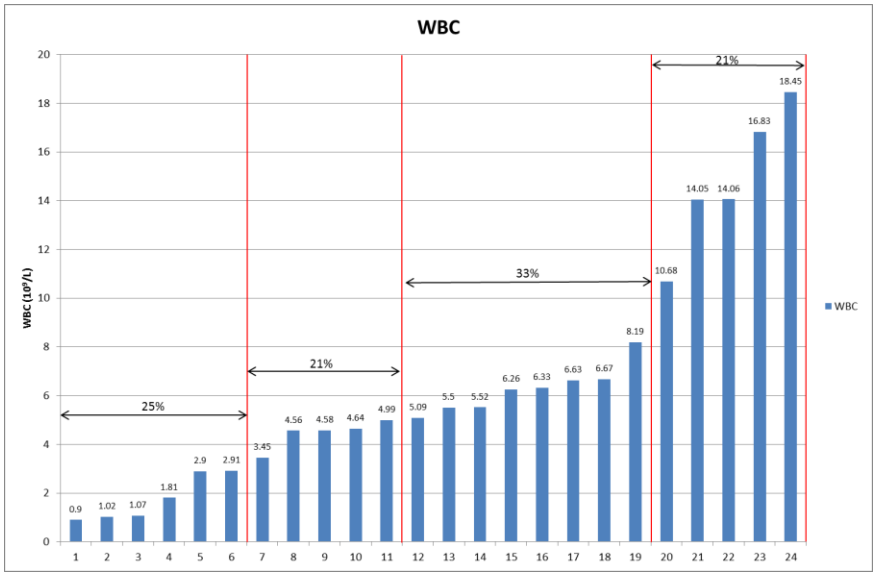
The range of specimens distributed for the Hb only option was:

Parameter	Jan – Dec 2016	Jan – Dec 2015
Hb (g/L)	59 – 173	53 – 145

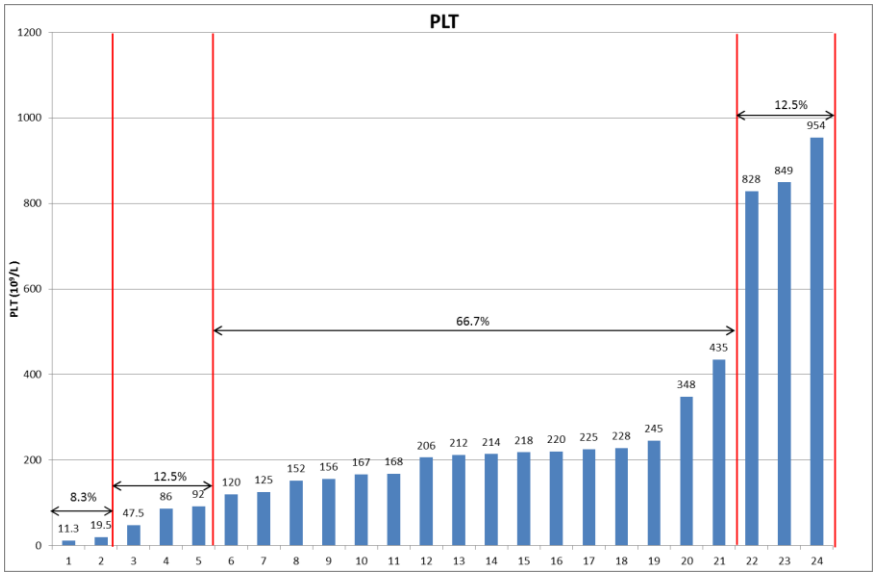
Results of analyses

All method trimmed mean values for surveys 1601FB to 1612FB

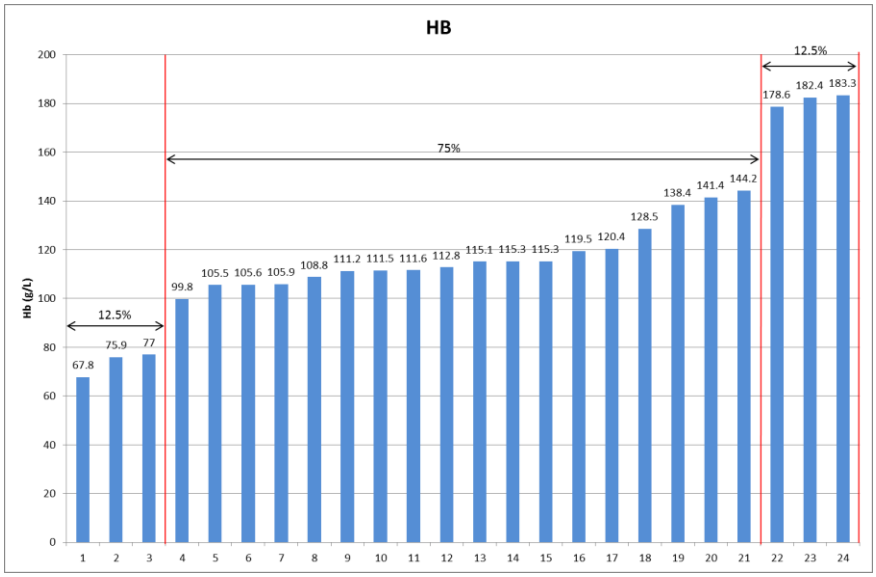
Distribution	Specimen	WBC (10^{9}/L)	RBC (10^{12}/L)	Hb (g/L)	PCV (L/L)	MCV (fl)	PLT (10^{9}/L)
16A	1601FB1	6.63	3.81	111.6	0.359	94.0	212
	1601FB2	1.02	3.57	105.9	0.337	94.3	86
16B	1602FB1	1.81	3.85	119.5	0.384	99.8	19.5
	1602FB2	5.52	4.02	120.4	0.388	96.7	218
16C	1603FB1	4.64	2.52	75.9	0.238	94.4	167
	1603FB2	8.19	3.46	99.8	0.324	93.8	435
16D	1604FB1	2.91	3.64	111.5	0.357	98.1	47.5
	1604FB2	6.67	3.86	108.8	0.354	92.0	245
16E	1605FB1	6.26	3.71	112.8	0.357	98.7	954
	1605FB2	18.45	6.23	183.3	0.590	94.7	206
16F	1606FB1	4.56	3.53	105.6	0.337	95.5	348
	1606FB2	5.09	3.69	111.2	0.359	97.3	225
16G	1607FB1	1.07	2.29	67.8	0.212	92.5	92
	1607FB2	14.06	4.82	144.2	0.470	97.7	849
16H	1608FB1	3.45	3.49	105.5	0.337	96.8	125
	1608FB2	4.58	4.46	138.4	0.441	99.2	152
16I	1609FB1	4.99	4.32	128.5	0.413	95.6	156
	1609FB2	4.05	6.01	182.4	0.579	95.2	168
16J	1610FB1	0.9	3.94	115.3	0.373	94.6	11.3
	1610FB2	6.33	3.84	115.3	0.374	97.4	220
16K	1611FB1	2.90	2.73	77.0	0.233	85.5	120
	1611FB2	10.68	4.89	141.4	0.460	94.3	828
16L	1612FB1	16.83	6.11	178.6	0.595	97.5	214
	1612FB2	5.50	3.81	115.1	0.371	97.3	228
MIN		**0.90**	**2.29**	**67.8**	**0.212**	**85.5**	**11.3**
MAX		**18.45**	**6.23**	**183.3**	**0.595**	**99.8**	**954**



WBC target values (1601 to 1612FB)



Platelet target values (1601 to 1612FB)



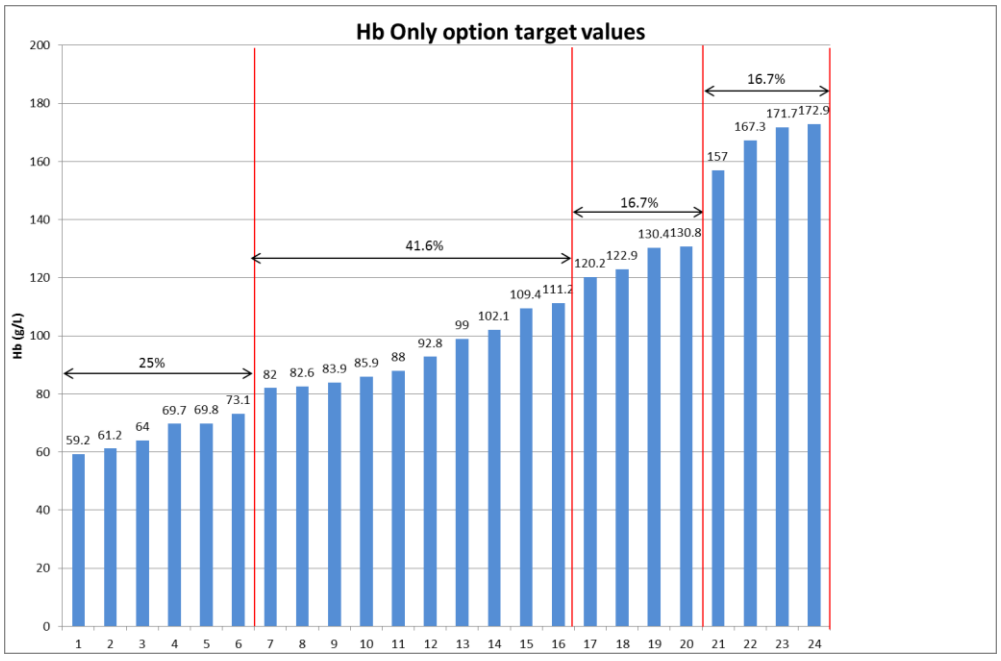
Hb target values (1601 to 1612FB)

Hb Only option in the Full Blood Count scheme

All method trimmed mean values for surveys 1601HB to 1612HB (Hb only option)

Distribution	Specimen	Hb (g/L)
16A	1601HB1	99.0
	1601HB2	111.2
16B	1602HB1	59.2
	1602HB2	122.9
16C	1603HB1	130.8
	1603HB2	82.0
16D	1604HB1	171.7
	1604HB2	85.9
16E	1605HB1	69.8
	1605HB2	109.4
16F	1606HB1	92.8
	1606HB2	130.4
16G	1607HB1	157.0
	1607HB2	69.7
16H	1608HB1	88.0
	1608HB2	172.9
16I	1609HB1	61.2
	1609HB2	82.6
16J	1610HB1	64.0
	1610HB2	102.1
16K	1611HB1	120.2
	1611HB2	83.9
16L	1612HB1	73.1
	1612HB2	167.3
MIN		**59.2**
MAX		**172.9**

Hb target values for Hb only option (1601HB – 1612HB)



Automated Differential Leucocyte Count (DL)

List of analytes

Differential leucocyte count as determined by automated instruments producing three and five population counts.

Registration for ADLC

	Laboratories		Systems	
	Total	**UK**	**Total**	**UK**
Dec 2015	935	647	1892	1229
Dec 2016	953	656	1998	1303

Specimens distributed

Survey material is purchased from R&D Systems, USA, and two specimens from seven different matrices or material types are available for each survey.

Survey material types for ADLC

Material type (matrix)	Differential population	Instruments
A	3 population	Sysmex K1000, KX21, K4500, pocH-100i, Cell-Dyn 1200,1600,1700,1800
B	3 population	Coulter AC*T Diff, Coulter MDII, ABX Micros, ABX Micros CRP, Siemens ADVIA 60, Diatron Abacus Junior 5, Nihon Khoden 3 population instruments
C	5 population	Cell-Dyn 4000, 3700, 3500, 3200, Sapphire, Ruby
D	5 population	Siemens ADVIA 120, Siemens ADVIA 2120
E	5 population	Coulter StkS, MaxM, GenS, HMX & LH series and Beckman Coulter UniCell DxH 800 & DxH600
G	5 population	ABX Pentra, ABX Pentra DX & DF and Coulter Ac*T5 Diff
J	5 population	Sysmex XE, XN, XS and XT series

Six surveys, 1601DL – 1606DL, have been distributed in the review period January to December 2016.

Results of analyses

Participants are given a statistical analysis of their total WBC in addition to the analysis of the automated differential leucocyte count, but this is not performance monitored.

The analysis of results for matrices D, G and J were sub-divided by instrument type for all 6 surveys, giving a total of 11 instrument groups.

Participants were performance assessed for neutrophil and lymphocyte counts.

Range of neutrophil (granulocyte) and lymphocyte values 1601 - 1606DL

Matrix	Range of Method Trimmed Means	
	Neutrophils (x 10^9/L)	Lymphocytes (x 10^9/L)
A	1.96 – 6.05	0.27 – 12.57
B	0.74 – 17.41	0.87 – 2.80
C (CD3200/4000)	1.53 – 16.27	1.18 – 3.69
D (Siemens Advia 120 etc)	1.26– 12.50	0.97 – 2.59
DA (Siemens Advia 2120)	1.28 – 12.55	1.05 – 2.65
E (Beckman Coulter)	1.89 – 14.18	1.45 – 4.89
G (Pentra 120 etc)	0.80 – 10.29	0.25 – 1.74
GA (Pentra 60 etc)	1.35 – 13.89	0.54 – 2.94
J (Sysmex XE/XT)	2.44 – 12.44	0.62 – 5.00
JA (Sysmex XS)	2.11 – 11.92	0.50 – 4.66
JB(Sysmex XN)	2.27 – 12.07	0.61 – 4.56

Reticulocyte Counting (RE)

List of analytes

Reticulocytes (10^9/L)

Registration for Reticulocyte Count

	Laboratories		Systems	
	Total	**UK**	**Total**	**UK**
Dec 2015	449	281	931	588
Dec 2016	453	277	952	586

Specimens distributed

Six distributions of 2 specimens each have been made in 2016. Commercial specimens are used for raised reticulocyte counts (4 specimens *per annum*), with normal and mid-range counts prepared in-house. A separate, commercial matrix (specimens REX1 and REX2) is supplied for the Beckman Coulter LH group of instruments. The use of this matrix is analogous to the separate, instrument specific matrices that are supplied for ADLC surveys.

Results of analyses

Automated methods results 1601RE – 1606RE (excludes Beckman Coulter LH)

Survey	Specimen	Number	Trimmed mean ($x10^9$/L)
1601RE	RE1	762	288.2
	RE2	755	25.9
1602RE	RE1	787	29.4
	RE2	787	29.2
1603RE	RE1	791	279.0
	RE2	791	90.0
1604RE	RE1	792	76.4
	RE2	797	29.5
1605RE	RE1	801	264.9
	RE2	799	26.1
1606RE	RE1	815	238.9
	RE2	816	65.5

Manual methods results 1601RE – 1606RE

Survey	Specimen	Number	Trimmed mean ($x10^9$/L)
1601RE	RE1	20	357.2
	RE2	20	19.5
1602RE	RE1	19	19.7
	RE2	19	22.9
1603RE	RE1	21	353.8
	RE2	21	68.6
1604RE	RE1	24	70.1
	RE2	24	24.6
1605RE	RE1	25	289.5
	RE2	25	23.1
1606RE	RE1	22	281.2
	RE2	22	78.0

Results for Beckman Coulter LH group 1601RE – 1606RE (REX matrix)

Survey	Specimen	Number	Trimmed mean ($x10^9$/L)
1601RE	REX1	61	39.0
	REX2	61	233.5
1602RE	REX1	52	33.6
	REX2	52	204.3
1603RE	REX1	39	36.1
	REX2	40	229.2
1604RE	REX1	36	36.3
	REX2	36	231.6
1605RE	REX1	38	36.5
	REX2	38	223.8
1606RE	REX1	34	218.0
	REX2	34	31.4

Blood Component Quality Monitoring (CM)

List of analytes

Hb, Hct and Platelet count at the concentrations found in therapeutic blood products
Hb (g/L)
Hct (L/L)
Platelet count ($x10^9$/L)

Registration for Blood Component Quality Monitoring

	Laboratories		Systems	
	Total	UK	Total	UK
Dec 2015	25	10	46	25
Dec 2016	27	12	47	23

The participant numbers reflect the small number of blood component processing laboratories.

Specimens distributed

Four distributions were made in 2016, each containing 2 unfixed red cell specimens for Hb and Hct and 2 specimens of fixed platelets for platelet counting. All materials are prepared in-house. Participants are given a common date for analysis, to minimise variation in performance due to the age of the survey material.

Results of analyses

Because of the small number of participants, analysis is against all methods data using the median as target value

Results for red cell survey material pools (1601CM – 1604CM)

	Haemoglobin (g/L)				Hct (L/L)			
Specimen	N	Median	Est SD	CV%	N	Median	Est SD	CV%
1601CM1	39	202	4.8	2.4	41	0.650	0.019	3.0
1601CM2	38	222	5.9	2.7	40	0.672	0.017	2.6
1602CM1	28	203	2.2	1.1	28	0.658	0.034	5.2
1602CM2	28	215	3.7	1.7	28	0.693	0.040	5.8
1603CM1	44	223	3.7	1.7	44	0.692	0.026	3.8
1603CM2	44	214	3.7	1.7	44	0.675	0.026	3.8
1604CM1	43	215	4.4	2.1	43	0.670	0.025	3.7
1604CM2	43	206	3.3	1.6	43	0.653	0.023	3.6

Results for platelet survey material pools (1601CM – 1604CM)

	Platelets (10^9/L)			
Specimen	N	Median	Est SD	CV%
1601CM3	40	2398	164	6.8
1601CM4	40	1875	215	9.2
1602CM3	26	1660	244	14.7
1602CM4	26	1721	200	11.6
1603CM3	42	2170	170	7.8
1603CM4	42	2134	214	10.0
1604CM3	43	1933	136	7.0
1604CM4	43	1653	111	6.7

Plasma Viscosity (PV)

List of analytes

Plasma viscosity (mPas)

Registration for Plasma Viscosity

	Laboratories	
	Total	**UK**
Dec 2015	50	46
Dec 2016	51	44

Specimens distributed

Distributions are made on a monthly basis, with two specimens of plasma per distribution. Survey material is prepared in-house from fresh frozen plasma from NHSBT, with the addition of glycerol to manipulate the viscosity, or from apheresis plasma from myeloma patients. 12 PV surveys were distributed between January to December 2016. No survey material pool was withdrawn during the year.

Results of analyses

All methods mean values for surveys 1601PV to 1612PV

Distribution	Sample no	PV (mPas)
16A	1601PV1	1.66
	1601PV2	2.68
16B	1602PV1	2.01
	1602PV2	2.10
16C	1603PV1	1.81
	1603PV2	1.71
16D	1604PV1	1.94
	1604PV2	3.82
16E	1605PV1	3.13
	1605PV2	1.64
16F	1606PV1	2.66
	1606PV2	2.30
16G	1607PV1	2.46
	1607PV2	1.98
16H	1608PV1	4.05
	1608PV2	2.16
16I	1609PV1	2.02
	1609PV2	2.45
16J	1610PV1	1.71
	1610PV2	1.67
16K	1611PV1	1.44
	1611PV2	1.70
16L	1612PV1	1.81
	1612PV2	3.42
MIN		**1.56**
MAX		**4.07**

The scheme was transferred to on-line operation from September 2016. At the same time, the system for analytical performance assessment was amended from the original CQAS method (monitoring the number of specimens with a deviation index value of equal to or greater than 3 in a rolling time window) to the standard UK NEQAS Haematology method, as used for all other UK NEQAS Haematology quantitative schemes. This is described in the Participants' Manual, available to download from the website (www.ukneqash.org).

Following review with the scheme statistician, the following scoring criteria were introduced from September 2016:

- Performance assessment is against an all methods trimmed mean rather than against instrument group target values
- DI values greater than 3.5 are truncated to 3.5 for the purpose of analytical performance score calculation, to avoid the participant incurring a high score because of a single 'blunder', e.g. transposition of specimens or results
- The multiplier value used to weight the DI values when calculating the score is 6, as for the FB, DL and RE schemes. This will be reviewed after 6 – 12 months for sufficient sensitivity to performance problems

Until the review is complete, participants with DI values of greater than 3 are reviewed as a part of the performance monitoring undertaken after each distribution, to ensure that major performance issues are not missed.

Erythrocyte Sedimentation Rate (ES)

List of analytes

Erythrocyte sedimentation rate (mm / hr)

Registration for ESR

	Laboratories		ES		ESX	
	Total	**UK**	**Total**	**UK**	**Total**	**UK**
Dec 2016	332	281	343	292	40	36

Participants may register for 2 separate modules: ES for non-Alifax technology instruments and ESX for Alifax instruments.

Specimens distributed

ES module: 3 distributions containing two whole blood specimens purchased commercially in each distribution have been made during the review period (1601ES – 1603ES).

ESX module: 3 distributions of 3 latex based survey material in each distribution, purchased commercially.

No survey material pool was withdrawn during the year.

Results of analyses

Instrument/Method Grouping for ESR

Group	Manufacturer	Model
Alifax	Alifax	Roller 20 Test1
Becton Dickinson Seditainer	Becton Dickinson	Seditainer Sedi-15 Sedi-20 Sedi-40
Sarstedt Sedivette	Sarstedt	SediPlus S200 SediPlus S20000 S-Sedivette
Starrsed	RRMechatronics	Starrsed AutoCompact Starrsed Compact Starrsed Interliner Starrsed Inversa 24M
Ves-matic	Diesse	VES-matic 20 VES-matic 30 VES-matic 30 plus VES-matic Easy
Ves-matic Cube	Diesse	VES-matic Cube 30 VES-matic Cube 80 VES-matic Cube 200 VES-matic Cube Track VES-matic Mini Cube
Westergren	Generic	Westergren
	Guest Medical	Dispette Dispette 2 Micro-Dispette

All methods mean values for surveys 1601ES to 1603ES

Distribution	Sample no	ESR (mm/hr)
1601ES	1601ES1	10.0
	1601ES2	16.2
1602ES	1602ES1	49.7
	1602ES2	15.3
1603ES	1603ES1	8.1
	1603ES2	40.1
MIN		**8.1**
MAX		**49.7**

All methods mean values for surveys 1601ESX to 1603ESX (Alifax users)

Distribution	Sample no	ESR (mm/hr)
1601ESX	1601ESX1	9.1
	1601ESX2	19.9
	1601ESX3	67.2
1602ESX	1602ESX1	12.8
	1602ESX2	29.1
	1602ESX3	89.4
1603ESX	1603ESX1	9.7
	1603ESX2	21.3
	1603ESX3	70.3
MIN		**9.1**
MAX		**89.4**

The scheme was added to the UK NEQAS Haematology scope of accreditation in January 2017 (application made August 2016).

Following review with the scheme statistician, the following scoring criteria were introduced:

- Performance assessment is against the method principle trimmed mean
- DI values greater than 3.5 are truncated to 3.5 for the purpose of analytical performance score calculation, to avoid the participant incurring a high score because of a single 'blunder', e.g. transposition of specimens or results
- The multiplier value used to weight the DI values when calculating the score is 6, as for the FB, DL and RE schemes. This will be reviewed after 6 – 12 months for sufficient sensitivity to performance problems

Until the review is complete, participants with DI values of greater than 3 are reviewed as a part of the performance monitoring undertaken after each distribution, to ensure that major performance issues are not missed.

A wide variation in the results returned was noted for the Vesmatic group of instruments for distributions 1601ES and 1602ES, and the group was withdrawn from performance assessment for both. Modified handling instructions for the survey material were issued for distribution 1603ES and this improved the results returned.

Blood Films for Morphology (BF) , Differential Counting (DF) and Parasite Identification (PA)

List of analytes

- Blood films for morphology comments
- Manual differential count
- Blood films for parasite screening and species identification

Registration for Blood films

	Blood Films		Parasite Films	
	Total	**UK**	**Total**	**UK**
Dec 2015	528	336	466	301
Dec 2016	521	330	464	297

Specimens distributed

Morphology films are stained by May-Grunwald-Giemsa. Although occasionally an unstained methanol fixed film may be distributed, none was distributed during the period January to December 2016. Parasite films are fixed in methanol or acetone and stained as appropriate for specific parasites by the Department of Clinical Parasitology, the Hospital for Tropical Diseases, London. There is close collaboration between UK NEQAS Haematology and UK NEQAS for Parasitology, which provides parasite films and teaching sheets for the scheme, and acts as reference for the parasite identification.

8 distributions of Blood Films for Morphology were made which include 4 manual differentials. There were 4 distributions of Blood Films for Parasites.

Morphology films distributed for surveys 1601BF to 1608BF

Specimen	Diagnosis
1601BF1	T-cell prolymphocytic leukaemia (T-PLL)
1601BF2	Multi-organ failure with renal impairment
1602BF1*	Burkitt lymphoma
1602BF2	Acute alcoholic hepatitis and renal failure
1603BF1	B-lineage ALL
1603BF2	Sickle cell anaemia
1604BF1*	Primary myelofibrosis
1604BF2	Normal
1605BF1	Megakaryoblastic transformation of primary myelofibrosis
1605BF2	Hb E- β^+ thalassaemia
1606BF1*	Sickle cell-β^0 thalassaemia
1606BF2	G6PD deficient (mild picture)
1607BF1	MPN/MDS
1607BF2	Infectious mononucleosis
1608BF1*	Mantle cell lymphoma
1608BF2	Leukaemoid reaction

* A differential count was requested on these four cases.

Parasite films distributed for surveys 1601PA to 1604PA

Specimen	Parasite
1601PA1	*P. falciparum* (percentage parasitaemia of 0.8%)
1601PA2	*P. malariae*
1602PA1	*P. ovale*
1602PA2	*P. vivax*
1603PA1	*P. falciparum* (thick film)
1603PA2	Negative
1604PA1	Microfilariae of *Loa loa* (thin film)
1604PA2	Negative

Results of analyses

Blood Film surveys:

The Blood Films for Morphology scheme is educational in objective with each report including the clinical background to the case and an expert comment from either Dr Parker-Williams, Professor Bain or Dr McNamara. At present, there is no scoring system although the requirement for performance assessment was highlighted in the recent UKAS inspection and models for scoring are being tested.

The majority of participants continue to correctly identify the significant morphological features in the blood films. A chart summarising the number of participants reporting each of the coded comments accompanies each Blood Film report allowing participants to compare their top five morphological observations against the overall findings for the distribution. The number of participants reporting films as unsatisfactory fluctuated between 0.6% and 5.8% with the leading reason being 'poor staining', closely followed by 'poor spreading'. Four out of the sixteen slides distributed during 2016 did not achieve an overall satisfactory film status greater than 95.0% which was poorer than the previous year. Problems with stain quality were acknowledged during the year and attributed to the pH of the de-ionised water and this was likely to have affected the stain quality of two of the four slide sets. Water from a different source is now being used and the pH and resulting stain colour has improved.

The cases chosen for 2016 included, as in previous years, a spread of different pathologies to test and inform participants. In the surveys the expert reviewers found a great deal of subject matter to debate and information to offer the participants as educational feedback.

There were a few instances which gave cause for concern. Dr Parker-Williams reported in survey 1602BF1 that a number of laboratories did not report the presence of blasts, "an important miss". Professor Bain pressed again in survey 1603BF1 for reporters to try for a diagnostic hypothesis in relation to the morphological features seen.

The WBC differential surveys still offer significant challenges due to the poor data returned. Dr Parker-Williams expanded on this in his review of survey 1601DF and has produced a teaching paper on the subject.

Participants are appreciative of these surveys and inform us that the films and reports continue to be frequently used for in-house teaching of all staff grades. The number of cases distributed was unchanged over previous years.

Blood Parasite surveys:

Another good range of cases provided by the Hospital for Tropical Diseases for the UK NEQAS Haematology Blood Films: Parasite distributions. As well as at least one of each of the four most common Plasmodium species, slides of *Loa loa* filariasis were also supplied. There were two *P. falciparum* cases, one of which was a thick film and one a thin with a moderate parasitaemia.

The number of participants was stable compared to the previous year with 464 this year compared to 466 in 2015. The percentage return rate of reports from surveys was approximately 95%. The number of unsatisfactory comments was quite varied and ranged from 0.23% to 26.4% for 1603PA2 a Giemsa stained thin film that was negative and 9.1% for 1604PA2 a Fields stained thick film that was also

negative. Participants remain appreciative of these surveys and continue to use the films and reports for in-house teaching. Extra slides, where available, are provided to participants on request.

The number of 'specimen unsatisfactory' comments returned for 1603PA2 was high enough to warrant consideration for withdrawal of this film from scoring. However given that 440 out of 443 returns gave a result and a consensus 'negative' was reported by 88% of participants, scoring was upheld.

In the summary for 1604PA2 Dr McNamara noted the importance of thick films for screening for parasites, but that 17% of laboratories films reported parasites present including malaria, microfilaria, trypanosomes and 'other', when this was in fact a negative film. He warned that a false diagnosis might lead to inappropriate treatment with potentially toxic side effects. The number of false positives reported was very similar to that seen for survey 1501PA2 released the previous year.

There was only one parasitaemia count exercise this year. The range reported was from 0.01% to >5.0%. Agreement between UK and non-UK laboratories was better than previous with the UK laboratories recording a median of 1.2% and non-UK laboratories a median of 1.3%.

The analysis of data for parasite identification and % parasitaemia is summarised below. The correct (reference) identification is shown in bold type; the identification of all *Plasmodium* species is confirmed by PCR.

Participants' results for Parasite Screening 1601-1604PA

Screening results	**1601PA1**	**1601PA2**	**1602PA1**	**1602PA2**	**1603PA1**	**1603PA2**	**1604PA1**	**1604PA2**
Negative for parasites	0	9	9	1	0	**388**	13	**359**
Positive for malaria	**446**	**435**	**432**	**441**	**432**	47	3	69
Positive for microfilaria	1	3	**1**	**0**	0	2	**424**	7
Positive for trypanosomes	0	2	**0**	**0**	2	1	0	1
Positive for other parasite	1	1	**0**	**0**	0	2	6	1
Babesia	0	0	**0**	**0**	0	0	0	0
Leishmania	0	0	**0**	**0**	0	0	1	0
Total no. of Reports	448	448	442	442	443	*443*	441	441

Participants' results for Parasite Identification 1601-1604PA[1]

Malaria Species	**1601PA1**	**1601PA2**	**1602PA1**	**1602PA2**	**1603PA1[2]**	**1603PA2**	**1604PA1**	**1604PA2**
P. vivax	39 (2)	20 (8)	167 (108)	**377 (235)**	2 (2)	14 (6)	0	26 (17)
P. ovale	60 (20)	18 (6)	**240 (152)**	40 (28)	1 (1)	3 (1)	0	1 (1)
P. falciparum	**353 (121)**	7 (2)	5 (2)	15 (7)	**397 (210)**	15 (7)	3 (1)	20 (12)
P. malariae	7 (2)	**377 (127)**	**14 (5)**	**6 (2)**	3 (1)	7 (3)	0	3 (2)
P. knowlesi	1 (1)	1 (0)	**0**	**0**	0	0	0	0
P. malariae / P. knowlesi	0	10 (3)	**0**	**0**	0	1 (1)	0	0
Non-Malaria Species								
Loa loa	0	0	**0**	**0**	0	1 (1)	**287 (194)**	4 (3)
Wuchereria bancrofti	0	0	**0**	**0**	0	1 (1)	88 (53)	1 (0)
Brugia	0	0	**0**	**0**	0	0	16 (10)	0
Trypanosoma brucei rhodesiense / gambiense	0	1 (1)	**0**	**0**	1 (0)	0	0	1 (1)
Trypanosoma Cruzi	0	1 (0)	**0**	**0**	0	1 (1)	0	1 (1)
Babesia	0	0	**0**	**0**	0	0	0	1 (1)

Notes: [1] the total number of participants returning a species is shown with those registered for identification in parentheses
[2] thick film

Percentage parasitaemia for films with trophozoites of *P. falciparum*

Slide	Labs	No.	Median	Estimated SD	Reported range	Reference value[1] (%)
1601PA1	All	347	1.2	0.82	0.01 – 71.0	0.8
	UK	247	1.2	0.82	0.0 – 5.0	

Notes: [1] **Reference values were provided by the Parasitology Dept, Hospital for Tropical Diseases, London**

There are two tiers to performance monitoring:

Screening: Participants are scored for each slide and given a cumulative score for the most recent six slides. An adverse score is given if the participant a) fails to identify the parasite type correctly (malaria, trypanosomes, microfiliaria), b) reports 'no parasites present' incorrectly or c) reports an additional parasite type present (eg. malaria and microfilaria). An alert (UP) letter is sent for the first out-of-consensus result and a PUP letter for the second out-of-consensus result. This means that a participant may receive a PUP letter for making errors in both slides of a single distribution.

Identification: Essentially unchanged from previous scoring routines, a participant who undertakes and is registered for species identification and who fails to report Plasmodium falciparum receives an alert letter and a participant who reports a percentage parasitaemia outside of +/-3SD from the median receives an alert letter.

Future Desirable Actions

- Scoring of the Blood Film surveys is proposed to commence in 2017/18, the system/s of scoring to be agreed after careful consideration at MSAG and pending shadow-scoring results. The next stage of the development of scoring will entail testing the system with a small number of volunteer laboratories.
- Participation scoring will be introduced for the DF surveys during 2017. Reporting of Manual Differential data to be reviewed.
- Removal of 'band forms' from the manual differential survey requirements to be implemented 2017

Scheme Expert Assessors' comments (provided for the Morphology SAG 2017 meeting)

Blood Films for Morphology surveys - Dr John Burthem & Ms Michelle Brereton

The scheme continues to offer an excellent slide range and is popular with laboratories. The required development of performance assessment is likely to introduce challenges, but overall this seems positive and will give us the chance to focus on aspects of performance (such as the failure to identify blast cells) in a more quantitative and structured way. The results of the pilot introduction will be of considerable interest, and will need careful scrutiny before formal introduction, but are likely to improve diagnostic quality.

The increasing use of digital return and interim reporting has clear advantages. The possible use of digital slides in some circumstances may also allow flexibility and better case mix, but the use of a suitable viewer and agreed image quality is paramount. The highlighting of features on the website is attractive but will introduce a further workload, the flexibility for paediatric cases is very attractive as a development if quality can be maintained.

Blood Films for Parasites surveys - Professor Peter Chiodini

It has been a pleasure to work with NEQAS Haematology on this scheme.

Performance varies by species distributed. When a straightforward P. falciparum is sent out, participants do very well (see 1603PA2). If a sample with late trophozoites is sent, the appearance of these larger parasite stages, plus Maurer's clefts in the red cell cytoplasm, can mislead microscopists into reporting P. vivax or P.ovale. See for example, 1601PA1. As with many diagnoses made by microscopy, familiarity and continued reinforcement by practice are key to malaria parasite examination. Attendance at the teaching course mentioned in Section 7 and use of on-line morphology resources will help in that respect.

Practice is also the way to achieve more accurate parasitaemias. This should not really be an issue as counting is easier than species discrimination and the BSH Guideline for malaria diagnosis explain how it should be done.

Regarding unsatisfactory films, this seems to be an issue mainly with negative films in which it can be difficult not to identify stain granules as malaria parasites.

Mis-identification of P. vivax and P. ovale continues in some laboratories, but the treatment of these is very similar so my main concern is that P. falciparum is not missed and its parasitaemia is counted accurately.

Finally, it was gratifying that so many laboratories were able to detect microfilariae when Loa loa was sent out, but about one third of them reported a different filarial species. Imported filariasis is becoming less and less common so going forward, skill in identifying precisely the microfilaria present may de facto devolve to specialist and reference laboratories. In the meantime, maintenance of skills in this area is to be encouraged.

Cytochemistry (CY)

List of analytes

Iron stain (Perls' stain)
Sudan Black B stain (SBB) or Myeloperoxidase (MPO)

Registration for Cytochemistry surveys

	Iron Stain		SBB/MPO	
	All	**UK**	**All**	**UK**
Dec 2015	174	149	34	23
Dec 2016	170	152	29	20

Specimens distributed

Unfixed blood films are distributed for SBB/MPO with a second set of methanol fixed films for Romanowsky staining to enable verification of the presence of blast cells. Methanol fixed films are distributed for Haemosiderin.

Cases distributed for Cytochemistry surveys

1601CY1	Haemosiderin: Bone Marrow Donor
1601CY2	Haemosiderin: Bone Marrow Donor
1602CY1	Sudan Black B: 67 male with AML
1602CY2	Sudan Black B: 3-year-old child with ALL
1603CY1	Haemosiderin: Bone Marrow Donor
1603CY2	Haemosiderin: Bone Marrow Donor
1604CY1	Sudan Black B: 9 year-old child with T-ALL
1604CY2	Sudan Black B: 25 year-old girl with pre B-ALL

Results of analyses

The number of participants for the Haemosiderin scheme is relatively stable now at 170 users from 174 in 2015. Returns are good with 91.5% and 88.1% of participants posting results for 1601CY and 1603CY respectively. The majority of participants continue to comment on the lack of adequate number of marrow particles in the marrow samples and the number of unsatisfactory comments were: 1601CY1 - 40.9%, 1601CY2 - 46.5%, 1603CY1 - 32.1%, and 1603CY2 - 60.9%. Dr Parker-Williams noted though that although the smears were aparticulate, iron-laden macrophages could readily be seen in all of the films distributed, especially 1601CY1 and CY2. The number of participants registered for Sudan Black B continues to fall from 53 in 2013 to 29 in 2016. Approximately 86% returned results for both 1602CY and 1604CY. Just 2 (7%) reported 1602CY1 and CY2 as unsatisfactory, but 7 (28%) gave 1604CY1 and 5 (7%) 1604CY2 as unsatisfactory. Dr Parker-Williams offered interesting and valuable educational commentaries for the SBB surveys.

Scheme Assessor's comments (for the MSAG 2016) – Dr J Parker-Williams

Haemosiderin:
There is little to report since my comments a year ago. There has been an improvement in the provision of particulate samples, but this cannot be guaranteed. I still have concerns on the interpretation of erythroblast iron and would it be worth a retrospective review of participants' stained films?

Sudan Black B:
Numbers remain static with 24 out of 29 participants returning a report. I suspect that several laboratories will only perform the SBB for the UK NEQAS Haematology surveys, it doesn't absolve them from using a verifiable control film. It is not good laboratory practice to state that their control film did not work. Even if the test films did demonstrate a positive SBB reaction in the mature myeloid cells.

Rapid Diagnostic Testing Malaria (RD)

List of analytes

Identification of malarial antigen

Registration for RDT Malaria surveys

	RDT Malaria	
	All	**UK**
Dec 2015	300	251
Dec 2016	303	251

Specimens distributed

Four surveys (2 specimens each) for Rapid Diagnostic Testing for Malaria were distributed at the same time as the Blood Films for Parasite Identification, to laboratories registered for this option.

Each survey comprises 2 sets of colour-coded and capped vials containing lysed and now freeze-dried, blood. The content of the vials have been confirmed by PCR testing. The lysates are prepared and tested by the Department of Parasitology, the Hospital for Tropical Diseases, London. Pre-acceptance testing is then further undertaken by UK NEQAS Haematology upon receipt of the material.

Specimens distributed for 1601RD – 1604RD

Specimen	Contents
1601RD1	*Plasmodium falciparum* (1200 parasites/µl)
1601RD2	*Plasmodium falciparum* (600 parasites/µl)
1602RD1	*Plasmodium falciparum* (5000 parasites/µl)
1602RD2	No malaria parasites present
1603RD1	*Plasmodium falciparum* (5000 parasites/µl)
1603RD2	No malaria parasites present
1604RD1	*Plasmodium falciparum* (4000 parasites/µl)
1604RD2	No malaria parasites present

Results of analyses

Overall, RDT reporting is performed well by the vast majority of laboratories using the test with between 94% and 96% of tests distributed being returned by participants. The number of participants registered on the scheme remains stable at around 300 for 2016.

The parasite concentrations ranged from 600 parasites per microlitre to 5000 parasites per microlitre and as such provided EQA material that tested kit sensitivity and user accuracy. Professor Chiodini noted in the 1601RD summary that the number of false negatives was disappointing for both RD1 and RD2, the RD1 material returning a figure of 15% false negatives over all kits. Again the need for care when checking for the appearance of very faint lines was highlighted.

New freeze-dried blood samples were introduced for 1604RD and the results returned were exceptionally good with 100% correct for both RD1 and RD2 test samples.

Results returned for 1601RD – 1604RD (correct result in bold)

	1601RD1	1601RD2	1602RD1	1602RD2	1603RD1	1603RD2	1604RD1	1604RD2
***P. falciparum* only**	**236**	**251**	**114**	1	**123**	0	66	0
Non *P. falciparum*	0	1	1	0	0	0	0	0
***P. falciparum* and/or mixed infection**	32	15	204	2	198	3	**256**	0
Negative	46	47	2	**319**	3	**319**	0	**320**
Total:	314	314	321	322	324	322	322	320

Note: the correct (reference) identification is shown in bold type

Scheme Assessor's comments (for the MSAG 2016) – Professor P Chiodini

I am pleased to say that performance in the RDTs scheme has been very good.

The only exceptions were 1601RD1 and 1601RD2 and my comment, noted above, should be heeded.

Moving to the use of freeze-dried material for the RDT distributions has proven successful and yielded samples which can readily be reconstituted and have long shelf lives. This will enable us to provide a wider range of parasitaemias in the future.

Abnormal Haemoglobins (AH)

List of analytes

Sickle screen (SCT)
Fraction identification (FID) in adult blood and simulated liquid capillary newborn blood, as appropriate
Quantitation of Hb A_2, Hb F and Hb S as appropriate
Assessment of quantitative results in terms of in-house reference range for Hb A_2 and Hb F
Suggested interpretation of results

Registration for Abnormal Haemoglobins

	Laboratories		Full participation		Liquid newborn option[1]		Sickle screen only	
	Total	UK	Total	UK	Total	UK	Total	UK
Dec 2015	474	275	317	147	36	30	157	128
Dec 2016	504	279	336	146	39	28	166	133

Laboratories may register methods for sickle screening test, fraction identification and quantitative assay of Hb A_2, Hb F and Hb S. There are 2 levels of registration: sickle screening test only and full participation with the option of receiving specimens simulating capillary blood from a newborn infant. Non-UK laboratories are allowed to register for the liquid newborn screening only, UK laboratories taking the liquid newborn specimens must be full participants in the Abnormal Haemoglobins scheme.

Laboratories registered for the liquid newborn option are included in the 'full participation' figures, unless they are non-UK laboratories registered for liquid newborn screening only.

Specimens distributed

6 distributions were made, comprising the following specimens:

- Three specimens of human whole blood in CPD-A1 anticoagulant for sickle cell screening, labelled SS1, SS2 and SS3. These specimens were sent to all participants, sickle screening and full participation. The sickle cell carrier blood used for SS survey material pools was used without dilution with normal blood.
- Three specimens of human whole blood in CPD anticoagulant, labelled AH1, AH2 and AH3, for fraction identification, fraction quantification (Hb A_2, Hb F and Hb S as appropriate), assessment of assay results and suggested interpretation of results. These specimens were sent to participants registered for full participation only, together with brief clinical details and full blood count details for each case.
- 6 distributions of 2 specimens each of normal human umbilical cord blood, some spiked with adult homozygous sickle cell or Hb CC blood, to simulate liquid blood specimens from a newborn infant. Clinical case details (age, ethnic background) are included with the specimens. Specimens are identified as LN1 and LN2.

The SS and AH specimens are not necessarily taken from the same pool of material, and participants are warned of this. The LN specimens are distributed separately from the remainder of the survey at the present time.

Specimens distributed for full participation 1601 – 1606AH

Survey	Specimen	Content
1601AH	1601AH1	31 year old Nigerian man whose partner is pregnant and a sickle cell carrier. No evidence of a haemoglobin variant or thalassaemia.
	1601AH2	34 year old Northern European lady attending for antenatal screening. No evidence of a haemoglobin variant or thalassaemia.
	1601AH3	27 year old Jamaican female undergoing antenatal haemoglobinopathy screening.
1602AH	1602AH1	30 year old Chinese male whose partner is pregnant and confirmed as a carrier for alpha zero thalassaemia
	1602AH2	24 year old African female undergoing antenatal haemoglobinopathy screening
	1602AH3	26 year old Nigerian female undergoing antenatal haemoglobinopathy screening
1603AH	1603AH1	29 year old Jamaican female undergoing antenatal haemoglobinopathy screening
	1603AH2	18 year old Asian male being investigated for a low haemoglobin level
	1603AH3	29 year old Nigerian female undergoing antenatal haemoglobinopathy screening
1604AH	1604AH1	36 year old patient of Nigerian origin, tested prior to general anaesthesia
	1604AH2	26 year old woman of Cypriot origin with a family history of beta thalassaemia, tested as part of antenatal screening
	1604AH3	31 year old woman of Irish origin screened as part of antenatal testing
1605AH	1605AH1	34 year old woman of African origin, tested as part of antenatal screening
	1605AH2	29 year old woman of African origin, tested as part of antenatal screening
	1605AH3	25 year old woman of Irish origin screened as part of antenatal testing
1606AH	1606AH1	18 year old woman of Turkish origin, tested as part of family screening, as her sister had been confirmed as a beta thalassaemia carrier
	1606AH2	25 year old woman of Greek origin, tested as part of antenatal screening and found to be a possible carrier of delta beta thalassaemia
	1606AH3	35 year old man of Nigerian origin whose partner is pregnant and a sickle cell carrier.

Liquid Newborn specimens distributed 1601LN – 1606LN

Survey	Specimen	Case details
1601LN	1601LN1	One day old male infant whose parents (of Jamaican origin) are both sickle cell carriers. The parents were tested in Jamaica and no written reports are available.
	1601LN2	One day old female infant whose parents are both of Greek origin. The mother is a carrier for beta thalassaemia but the father has not been tested.
1602LN	1602LN1	One day old Jamacian male infant. The baby's mother is known to have sickle cell anaemia but his father's test results are not known.
	1602LN2	One day old female infant of African origin. The mother was not tested for sickle status during pregnancy but has a report from a previous test stating she is a sickle carrier. The father's test results are not known.
1603LN	1603LN1	One day Asian male infant whose parents are both carriers for beta thalassaemia.
	1603LN2	one day old Nigerian female infant whose mother is a known sickle cell carrier. The father is said to be a carrier for HbC but no report is available.
1604LN	1604LN1	One day old Nigerian male infant. His mother is known to be a carrier for Hb S and his father a carrier for Hb C.
	1604LN2	One day old male infant of Jamaican origin. Both parents are carriers for Hb S.
1605LN	1605LN1	One day old male infant of Caribbean origin. Both parents are said to be carriers for sickle cell and the mother's results confirm this but the father is unavailable for testing.
	1605LN2	One day old female infant of Bangladeshi origin. Both parents are said to be carriers of beta thalassemia.
1606LN	1606LN1	One day old male infant of Nigerian origin. Both parents are known to be carriers for HbS. The couple declined the offer of prenatal diagnosis
	1606LN2	One day old female infant of Turkish origin. Her mother is a carrier for HbS and her father for beta thalassemia trait. The couple declined the offer of prenatal diagnosis

Results of analyses

Participants are scored for Sickle cell sceening, Hb A_2 and Hb S quantitation. Analytical performance scores for Hb A_2 and Hb S are calculated in the same way as for the FBC scheme, SCT is scored with 50 penalty points for an incorrect result. There is no analytical performance scoring for LN; however, any UK laboratory returning an incorrect result is contacted directly.

There are no non-participation issues, with a mean return rate of over 95% for all participants during the year. The participation rate for UK full participants is even higher than this.

Sickle cell screening results, for specimens 1601SS – 1606SS, all labs. The consensus result is shown in bold type.

Specimen	No.	SCT Pos	SCT Neg	% incorrect
1601SS1	403	1	**402**	0.2
1601SS2	401	**398**	3	0.7
1601SS3	402	3	**399**	0.7
1602SS1	408	**402**	6	1.5
1602SS2	407	**400**	7	1.7
1602SS3	407	3	**404**	0.7
1603SS1	410	**405**	5	1.2
1603SS2	407	5	**402**	1.2
1603SS3	407	7	**400**	1.7
1604SS1	396	**391**	5	1.3
1604SS2	396	**392**	4	1.0
1604SS3	395	7	**388**	1.8
1605SS1	403	3	**400**	0.7
1605SS2	402	2	**400**	0.5
1605SS3	402	**398**	4	1.0
1606SS1	400	3	**397**	0.8
1606SS2	399	**396**	3	0.8
1606SS3	400	**397**	3	0.8

Fraction identification results, for surveys 1601AH – 1606AH, all labs

Specimen	No.	Essential fractions	Fraction ID		
			Correct	Incorrect[1]	Hb A not recorded[2]
1601AH1	316	A	302	5	9
1601AH2	316	A + F	297	10	9
1601AH3	316	A + S	298	9	9
1602AH1	316	A	296	10	10
1602AH2	316	A + S	286	20	10
1602AH3	316	A + F	288	18	10
1603AH1	319	A + S	294	15	10
1603AH2	319	A	304	9	6
1603AH3	319	A + C	256	58	2
1604AH1	312	A	291	11	10
1604AH2	312	A	292	8	12
1604AH3	312	A + F	291	12	9
1605AH1	321	A + C	264	51	6
1605AH2	321	A + S	302	12	7
1605AH3	321	A + F	302	12	7
1606AH1	319	A	305	8	6
1606AH2	319	A + F	303	9	7
1606AH3	319	A	304	8	7

Note

1. Includes participants who did not supply any fraction identification and participants reporting a non-specified fraction. In many cases, the latter group are unable to identify further with the techniques available to them and refer all abnormal variants to another laboratory for confirmation.
2. These participants did not note the presence of Hb A but otherwise provided the correct fraction identification. In all cases, this was due to a clerical oversight rather than the fraction not being identified.

Fraction identification results for distributions 1601LN – 1606LN

Specimen	No.	Result	Correct	Incorrect
1601LN1	38	FA	37	1
1601LN1	38	FA	38	0
1602LN1	39	FAS	39	0
1602LN2	39	FA	39	0
1603LN1	39	FA	39	0
1603LN2	39	FAS	39	0
1604LN1	39	FA	39	0
1604LN2	39	FA	39	0
1605LN1	38	FAC	36	2
1605LN2	38	FA	38	0
1606LN1	38	FA	38	0
1606LN2	38	FAS	37	1

Hb A_2 quantitation 1601 – 1606AH – all methods results, all labs

Specimen	No. [1]	Mean Hb A_2 %	GCV	Reported range [2]
1601AH1	336	2.5	7.49	1.9 – 5.2%
1601AH2	336	2.4	7.53	1.6 – 4.4%
1602AH1	341	2.4	9.11	1.6 – 3.1%
1602AH3	337	1.9	11.53	1.1 – 4.3%
1603AH2	340	2.5	8.15	1.4 – 4.4%
1604AH1	337	2.9	6.30	1.9 – 3.7%
1604AH2	338	3.0	6.05	1.9 – 3.9%
1604AH3	338	2.5	7.49	1.7 – 3.2%
1605AH3	345	2.2	8.92	1.2 – 4.8%
1606AH1	350	2.6	7.40	0.0 – 206.0%
1606AH2	352	2.1	9.45	0.3 – 2.6%
1606AH3	351	2.3	8.15	0.9 – 3.0%

Note:

1. The number of Hb A_2 quantitation results is greater than the number of participant laboratory returns for the distribution because some laboratories register more than one quantitation method or instrument. This also applies to Hb F and Hb S quantitation.
2. The extreme range of results for some specimens (e.g. 1606AH1) may reflect clerical errors, including transposition of specimens or results, reporting with the decimal point in the wrong place and reporting Hb A% instead of Hb A_2%.

Hb F quantitation 1601AH-1606AH – all methods results, trimmed mean >3%, all labs

Specimen	No.	Mean Hb F % [1]	GCV	Reported range [2]
1601AH2	337	10.6	8.14	1.1 – 13.5%
1602AH3	333	21.3	8.82	0.0 – 25.5%
1604AH3	337	6.9	8.98	0.4 – 8.7%
1605AH3	344	4.9	10.65	0.0 – 8.5%
1606AH2	349	14.2	7.54	0.4 – 17.7%

Note:

1. Specimens with all methods trimmed mean (ALTM) results of <3% are not included as many participants report their results as 'less than 1 or 0.5' once the ALTM falls below this level, skewing statistical assessment.
2. The extreme range of results for some results may reflect clerical errors, transposition of specimens or results, or participants reporting '0.0%' when in fact they had not assayed the Hb F%

Hb S quantitation 1601AH-1606AH – all methods results, all labs

Specimen	No.	Mean Hb S %	GCV	Reported range [1]
1601AH3	328	23.3	4.12	24.1 – 42.4%
1602AH2	323	32.4	5.08	26.4 – 61.9%
1603AH1	330	24.9	4.91	20.1 – 30.5%
1605AH2	322	33.1	3.86	4.4 – 36.7%

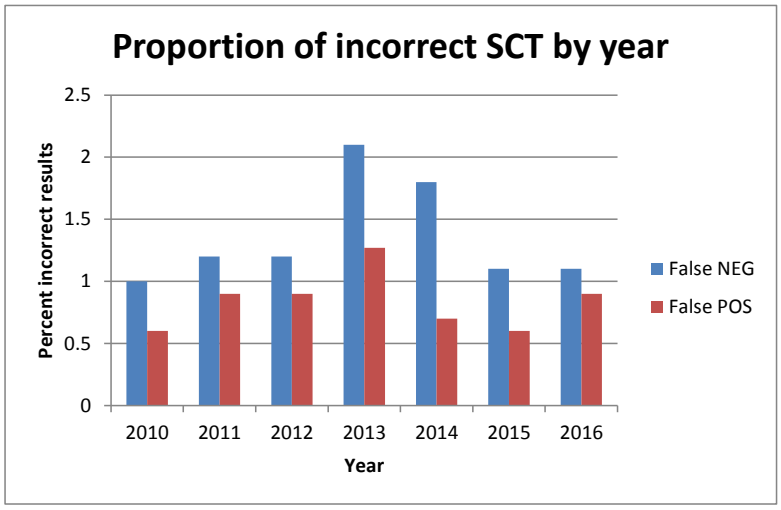
Note:

[1] The extreme range of results for some specimens (e.g. 1605AH2) reflects clerical errors

General Performance Issues

Analysis of overall performance in sickle cell test (SCT) shows that 0.94% (34/3626) of negative SCT results were incorrectly reported as positive and 1.11% (40/3619) of positive SCT results were incorrectly reported as negative. The proportion of incorrect results remains stable. The incorrect results are not associated with any particular method or kit and are returned by UK as well as non-UK participants.

Trends in incorrect sickle solubility tests reported.



The incorrect fraction ID results reported include clerical errors, participants overlooking to report Hb A, participants not reporting any fraction identification results and participants reporting non-specified fractions. An increasing number of participants are using the 'non-specified' fraction when any variant, including Hb S, is present and some mark both Hb S and Hb C because their analyser does not differentiate between the two. These laboratories typically screen only to differentiate abnormal from normal specimens, referring the abnormal ones for confirmation at another hospital. There are no persistent fraction identification problems for either AH or LN specimens.

Two Hb C carrier specimens were distributed during the year (1603AH3 and 1605AH1). The number of laboratories not reporting the fractions essential for diagnosis was high for both these specimens (totals of 58 and 51 respectively, compared to between 2 and 20 for other specimens).

For specimen 1603AH3, 14 UK laboratories did not report the Hb pattern essential for diagnosis (Hb A + Hb C):

- 4 reported Hbs A, A2 and F only: 3 used the correct interpretation, 1 reported the specimen as normal
- 3 reported Hb S but not Hb C present: 1 interpreted the result as sickle cell trait, 2 would follow up with a second specimen or referral for further investigation
- 2 reported a non-specified fraction but not Hb C present, to be referred for further investigation. This result may represent an 'unable to identify' report.
- 2 did not report either Hb A or Hb C present: one noted possible Hb C carrier in a written comment, both would have referred the specimen for further investigation
- 1 reported Hb C or Hb E present, but interpreted the case as Hb C
- 2 reported Hb A and Hb C but also noted a non-specified fraction present: one gave the interpretation of an Hb C carrier, the other would have referred the specimen for confirmatory testing

For specimen 1605AH1, the same number of UK laboratories (14) did not report the Hb pattern essential for diagnosis (Hb A + Hb C); however, the majority of the out of consensus results related to reporting an unidentified or non-specified fraction that would be sent for further testing:

- 2 reported Hb C or Hb E present, but gave the correct interpretation of Hb C carrier
- 1 reported Hb S but not Hb C present
- 2 reported unexpected fractions in addition to Hb A and Hb C
- 9 reported Hb A with a non-specified fraction, the majority (7) used an analyser that does not differentiate Hb S and Hb C, 1 noted a possible Hb C in a written comment and 1 an unidentified variant for further testing

Participants have been asked to suggest an interpretive comment for their AH and LN results, using a set of coded comments. This part of the scheme is not subject to performance monitoring and is not reviewed here as the quantity of information is very large. Further information may be found in the individual survey reports for 1601AH – 1606AH and 1601LN – 1606LN upon request.

Newborn Sickle Screening (NH)

List of analytes
Clinically significant Hb variants in umbilical cord blood for identification
Interpretation of fraction identification

Registration for Newborn Sickle Screening

	Laboratories	
	Total	**UK**
Dec 2015	28	22
Dec 2016	28	22

The participant base includes 16 UK primary Screening laboratories: 13 in England, one in Scotland, one in Wales and one in Northern Ireland; other participants include laboratories in the UK and Europe. Two UK primary screening laboratories have 2 instruments registered; this gives a total of 18 sets of results identified as UK Screening Laboratory results.

The number of participants has stabilised following the reduction as a result of non newborn screening laboratories opting to receive the liquid newborn (LN) specimens in the AH scheme instead of the NH dried blood spot specimens, which they do not handle in clinical practice.

Specimens distributed
Specimens are distributed as dried blood spots of umbilical cord blood, which has been EDTA anticoagulated. 3 specimens are distributed with each survey, with ethnic origin, birthweight and gestation. Surveys are distributed monthly.

Specimens are validated for testing by HPLC, IEF, capillary electrophoresis (CE) and tandem mass spectrometry (TMS).

Specimen quality has been reported as satisfactory. 1603NH3 was withdrawn from scoring because of a lack of consensus between participants.

Results of analyses

One newborn screening laboratory reports their results in line with their national protocol for haemoglobinopathy screening in newborn infants, which is designed to detect the presence of sickle cell disease only. This participant's results are classed as within consensus if they correlate with the presence or absence of sickle cell disease.

Participants are scored for non-participation, analytical performance and interpretation of results.

There are no unresolved participation issues.

There has been a total of 7 out of consensus fraction identification results returned, compared to 6 in 2015, 11 in 2014, 15 in 2013, 10 in 2012, 5 in 2011, 6 in 2010, 4 in 2009 and 7 in 2008.

Where a laboratory has made an analytical error, they are not scored for interpretation.

Fraction identification results for 1601NH – 1612NH (January – December 2016, all participants)

Specimen	Consensus result	No. of returns	Within consensus	Outwith consensus
1601NH1	FA	31	31	0
1601NH2	FA		31	0
1601NH3	FAS		31	0
1602NH1	FA	31	31	0
1602NH2	FAS		31	0
1602NH3	FAC		31	0
1603NH1	FAS	29	29	0
1603NH2	FAC		26	3 [1]
1603NH3	FAE		*	*
1604NH1	FS	28	27	0
1604NH2	FAS		27	1 [2]
1604NH3	FA		26	2 [2,3]
1605NH1	FA	29	29	0
1605NH2	FAS		29	0
1605NH3	FA		29	0
1606NH1	FA	30	30	0
1606NH2	FAS		30	0
1606NH3	FAE		29	1 [4]
1607NH1	FAS	30	30	0
1607NH2	FA		30	0
1607NH3	FA		30	0
1608NH1	FS	29	29	0
1608NH2	FA		29	0
1608NH3	FAS		29	0
1609NH1	FA	30	30	0
1609NH2	FAS		30	0
1609NH3	FA		30	0
1610NH1	FA	28	28	0
1610NH2	FAS		28	0
1610NH3	Hb A only (adult specimen)		8	0
1611NH1	FA	30	30	0
1611NH2	FAS		30	0
1611NH3	FAS		30	0
1612NH1	FAC	30	30	0
1612NH2	FAS		30	0
1612NH3	FAS		30	0

Notes – performance issues relating to UK laboratories:

[1] 1603NH2 was a challenging specimen with a very low Hb A%; some labs were unable to visualise Hb A

[2] One UK newborn screening laboratory transposed specimens 1604NH2 and NH3

[3] One UK newborn screening laboratory reported 1604NH3 as FAS

[4] One UK non-screening laboratory did not report Hb E in 1606NH3

*1603NH3 was withdrawn from scoring because of a lack of consensus between participants

DNA Diagnostics for Haemoglobinopathies (DN)

List of analytes

Alpha and beta globin mutational analysis
Interpretation of results
Compliance with reporting recommendations
Use of nomenclature

Registration for DNA Diagnostics for Haemoglobinopathies

	Laboratories	
	Total	**UK**
Dec 2015	48	10
Dec 2016	47	10

Laboratories may register for alpha and / or beta globin mutational analysis. Because of the specialist nature of the investigations, this scheme has a large number of non-UK participants. The amount of survey material is limited, meaning that a waiting list of non-UK participants is in operation.

Specimens distributed

Three distributions of two specimens are scheduled each participation year. Survey material is DNA in TE buffer and is waste material remaining after diagnostic testing. All material is supplied without patient identifiers. The specimens are supplied with accompanying clinical and laboratory details for use in interpretation of the results.

The final distribution of 2015 was held back until January 2016 to avoid delay in the Christmas post and distributed as survey 1601DN. Two further distributions were made in 2016 (1602DN and 1603DN). 1603DN1 was withdrawn because of failure of agreement of the pre-acceptance testing with the expected content of the material.

DNA Diagnostics for Haemoglobinopathies specimens (1601DN – 1603DN)

Specimen	Contents	Case details
1601DN1	Alpha genotype: $-\alpha^{3.7}/--^{SEA}$ Beta genotype: β^A/β^A	Male, 16 yrs, Asian origin. Referred for investigation of anaemia.
1601DN2	Alpha genotype: $\alpha\alpha/\alpha\alpha$ Beta genotype: $\beta^A/\beta^{Cd8(-AA)}$	Male, 25 yrs, Turkish origin. Partner of pregnant lady who is a known sickle cell carrier.
1602DN1	Alpha genotype: $-\alpha^{3.7}/\alpha\alpha$ Beta genotype: β^A/β^C	Female, 16 yrs, African origin. Patient is pregnant and arrived alone in the country as a refugee. Her partner, of Nigerian origin, is unavailable for testing.
1602DN2	Alpha genotype: $\alpha\alpha/\alpha\alpha$ Beta genotype: $\beta^A/\beta^{IVS1\text{-}6(T>C)}$	Male, 57 yrs, Italian origin. The eldest child (male, 30 yrs) of this subject recently required transfusion due to anaemia.
1603DN1	Withdrawn	
1603DN2	Alpha genotype: $\alpha\alpha/\alpha\alpha$ Beta genotype: β^A/β^A	Caucasian male, 29yrs of age. The patient is the partner of a pregnant woman with an Hb A2 value of 3.6%.

The specimen quality is generally marked as satisfactory by participants. There are occasional comments that the amount of DNA supplied is insufficient, although the majority of participants still return results.

Results of analyses

1601DN

Alpha genotype results for specimen 1601DN1
41 participants undertook alpha genotyping. 36 of the 41 returned the correct result, $-\alpha^{3.7}/\!\!--^{SEA}$.

A further 3 participants obtained the correct result, but the genotype was incorrectly annotated:
1 participant reported $-\alpha^{3.7}/SEA$
1 participant reported $\alpha^{0}SEA/-\alpha3.7$
1 participant reported $--^{SEA}/-^{3.7}\alpha$

1 of the 41 participants who undertook alpha genotyping gave an incorrect result and reported the result as $-\alpha^{3.7}/-\alpha^{3.7}$.
1 further participant was unable to reach a final conclusion due to insufficient specimen. This participant reported:
'Unconfirmed alpha genotype of HbH --/$-\alpha^{3.7}$ or homozygous alpha plus thalassaemia , e.g. $-\alpha^{3.7}/-\alpha^{3.7}$. This participant requested a further specimen for confirmation but none was available.

Beta genotype results for specimen 1601DN1
37 participants undertook beta genotyping and all reported the correct result, β^{A}/β^{A}.

Alpha genotype results for specimen 1601DN2
39 participants undertook alpha genotyping on this specimen and all reported the expected genotype, $\alpha\alpha/\alpha\alpha$.

Beta genotype results for specimen 1601DN2
41 participants undertook beta genotyping, 37 of which gave the expected result, $\beta^{A}/\beta^{Cd8(-AA)}$.
Two participants obtained the correct genotype result but gave incorrect annotation-
One participant reported the mutation as $\beta^{A}/\beta^{Fr8(-AA)}$ and another as $\beta^{A}/\beta^{Codon8AA}$.
The remaining two participants gave incorrect genotyping results-
one participant reported the genotype as $\beta^{A}/\beta^{Cd8(-11)}$ and another as $\beta^{A}/\beta^{Cd9(-AA)}$.

1602DN

Alpha genotype results for specimen 1602DN1
36 participants undertook alpha genotyping. 35 of the 36 returned the correct result, $-\alpha^{3.7}/\alpha\alpha$.

A further participant obtained the correct result, but the genotype was incorrectly annotated as $-^{3.7}/\alpha\alpha$.

Beta genotype results for specimen 1602DN1
41 participants undertook beta genotyping, 40 participants returned the correct result, β^{A}/β^{C}.
1 participant reported the genotype as $\beta^{A}/\beta^{Cd7(G>A)}$.

Alpha genotype results for specimen 1602DN2
37 participants undertook alpha genotyping on this specimen and all reported the expected genotype, $\alpha\alpha/\alpha\alpha$.

Beta genotype results for specimen 1602DN2
41 participants undertook beta genotyping, 38 of which gave the expected result, $\beta^{A}/\beta^{IVS1-6(T>C)}$.
Two participants obtained the correct genotype result but gave incorrect annotation, one participant reported the mutation as β^{A}/β^{IVS1-6} and another as $\beta^{A}/\beta^{IVS-1+6T>C}$
The remaining participant reported the results as β^{A}/β^{+} or β^{+}/β^{+}.

1603DN

Alpha genotype results for specimen 1603DN2

43 participants undertook alpha genotyping and 42 returned the correct result: $\alpha\alpha/\alpha\alpha$.
One participant reported the result as $\alpha\alpha/\alpha\alpha^{St\ Claude}$.

Beta genotype results for specimen 1603DN2

42 participants undertook beta genotyping, 40 participants returned the expected result, β^A/β^A.
One participant reported the correct genotype but with incorrect annotation, reporting β/β.
1 participant reported the genotype as $\beta^A/\beta^{IVS2\text{-}74(G>T)}$ and qualified their findings by interpreting $\beta^{IVS2\text{-}74(G>T)}$ as a polymorphism which has no clinical effect, hence this represented a normal beta genotype.

All participants receive the model answer for each specimen when the distribution closes, a summary report and a personalised report of their performance.

Red Cell Enzymes - G6PD (G6)

List of analytes

G6PD screening test
G6PD quantitation
Assessment of quantitation by the participant in terms of in-house reference range

Registration for red cell G6PD

	Laboratories		Screen		Assay	
	Total	**UK**	**Total**	**UK**	**Total**	**UK**
Dec 2015	236	136	143	106	107	53
Dec 2016	233	126	137	100	135	51

Laboratories may register for screening test, quantitative assay, or both. The number of UK participants has declined as laboratories centralise services. Note that for quantitative assay, the number of non-UK laboratories registered now exceeds the number of UK laboratories.

Specimens distributed

Six distributions (1601G6 – 1606G6) of 2 specimens each have been made in the review period. 7 survey specimens were prepared from human whole blood in CPD anticoagulant and 5 from defibrinated sheep whole blood. The sheep donations are G6PD deficient in human terms.

Results of analyses

G6PD Screening results, all labs (accepted target results in bold type)

Specimen	Survey trimmed mean IU/gHb at 30°C	Screening Results (Number of laboratories)		
		Deficient	**Not deficient**	**Intermediate**
1601G61	10.4	2	**126**	1
1601G62	1.3	**121**	2	**6**
1602G61	1.2	**112**	1	**16**
1602G62	7.5	2	**126**	1
1603G61	9.4	3	**125**	1
1603G62	1.0	**124**	2	3
1604G61	8.1	0	**119**	5
1604G62	8.5	0	**121**	3
1605G61	6.7	2	**116**	4
1605G62	7.0	2	**117**	4
1606G61	1.3	**98**	5	**22**
1606G62	1.1	**99**	4	**22**

G6PD quantitative assay results at 30°C

Specimen	No.	Trimmed mean IU/gHb at 30°C	SD	Reported Range
1601G61	61	8.5	1.0	2.0 – 11.5
1601G62	54	1.1	0.3	0.0 – 14.4
1602G61	56	1.2	0.3	0.5 – 6.7
1602G62	62	7.5	1.1	4.5 – 11.9
1603G61	63	9.4	1.4	5.0 – 230.0
1603G62	53	1.0	0.3	0.4 – 10.6
1604G61	62	8.1	1.0	4.7 – 12.2
1604G62	62	8.5	1.2	5.5 – 11.5
1605G61	53	6.7	1.0	4.1 – 9.4
1605G62	53	7.0	1.1	4.0 – 10.0
1606G61	51	1.3	0.3	0.5 – 4.8
1606G62	51	1.1	0.3	0.5 – 4.5

G6PD quantitative assay results at 37°C

Specimen	No.	Trimmed mean IU/gHb at 37°C	SD	Reported Range
1601G61	58	10.4	2.6	0.9 – 22.0
1601G62	56	1.3	0.5	0.4 – 6.0
1602G61	58	1.5	0.5	0.7 – 11.6
1602G62	59	9.2	1.9	1.1 – 18.6
1603G61	58	11.3	2.3	1.0 – 19.5
1603G62	58	1.2	0.4	0.0 – 7.1
1604G61	60	9.8	2.2	1.0 – 212.0
1604G62	60	10.4	2.8	1.1 – 229.0
1605G61	57	8.6	2.3	4.2 – 208.0
1605G62	57	9.1	2.4	4.9 – 179.0
1606G61	61	1.6	0.5	0.8 – 12.0
1606G62	61	1.4	0.5	0.7 – 10.0

Note: the reported range is as submitted by participants and includes typographical errors (e.g. missed decimal point) and results reported in the incorrect units.

Participants are scored for non-participation and analytical performance (screening and quantitative assay. Participation was approximately 95% throughout the year.

For screening test results, 3.4% (30/880) of results for 'not deficient' specimens were reported as deficient / intermediate (compared to 2.6% for 2015, 2.3% for 2014, 3.8% for 2013, 4.0% for 2012, 4.6% for 2011, 4.3% for 2010 and 4.4% for 2009).

The scheme now includes the quantitative assay result on the screening report page, for reference for laboratories that undertake screening only. Following discussion with the SAG, the scheme classes both deficient or intermediate as the target result for screening if the assay result is greater than 1.0 IU/gHb.

The ratio of laboratories using 30°C compared to 37°C as the temperature at which results are reported to clinicians was 51:61 at December 2016, compared to 58:61 in 2015, 56:52 in 2014 and 53:47 in 2013, with a continued increase in the number of laboratories using 37°C, which may reflect an increased use of automated analysers for these assays. There are now more non-UK than UK laboratories registered for quantitative assay.

Digital Morphology

The UK NEQAS Haematology Digital Morphology CPD scheme is a Web based system, which uses digital images to support the development of morphology skills for healthcare scientists and clinicians. High resolution, 'stitched' images (virtual slides) are posted with a brief outline of patient history and limited blood results. Participants are asked to examine the image, select five main features and suggest a diagnosis where possible. Participants might also be asked to indicate what action they might take in response to their findings and, with some cases, to indicate the level at which they practise. Results are submitted on-line and initial, objective feedback is provided immediately with image annotations and additional narrative. A second tier of feedback is provided once the data submitted by all participants has been analysed.

2993 licences were purchased in 2016, demonstrating a continued increase in licence requests (2988 in 2015). The number of participants engaging with each case varies but averages at around 900 per case over the last 6 cases.

UK NEQAS for General Haematology continues to work closely with Dr John Burthem and Ms Michelle Brereton at the Manchester Royal Infirmary in the provision of the cases and the accompanying narrative text.

The following cases have been issued in 2016:

1601DM	SCID with maternal GVHD - 2 week baby
1602DM	South East Asian Ovalocytosis
1603DM	Primary Myelofibrosis
1604DM	Bone Marrow infiltration by carcinoma
1605DM	CLL with Beta Thalassaemia trait
1606DM	TBA

This scheme is offered for educational purposes and there is no performance monitoring.

Pilot and Other Schemes in Development

Nucleated RBC Counting Pilot

This became a scheduled pilot scheme in 2014, with 2 distributions of 2 specimens each, using commercial material. The availability of survey material and level of interest from participants means that only Sysmex X class analysers and Beckman Coulter instruments were covered by the scheme in 2015. Because of changes to the models of Beckman-Coulter analysers on the market, the scheme was not offered to Beckman-Coulter users from April 2016 and will not be until alternative survey material is available (anticipated later in 2017).

The number of laboratories registered (December 2016) was 141 (144 in 2015, 97 in 2014), returning results from a total of 394 analysers (292 in 2014).

Data return is by fax and hard copy reports are provided. Reports show summary data with non-parametric statistical analysis and 'your results', without any performance scoring.

The scheme will continue as a pilot for 2017 and its progress will be reported to the General (automated counting) SAG.

Pre- and Post-Analytical Quality Monitoring Service

This pan-UK NEQAS service has been set up by a working group chaired by the Scheme Director. Over 250 sites in the UK and Republic of Ireland enrolled in the extended pilot scheme in 2015/16 and the service will be launched fully in April 2017. There are major challenges in data gathering and reporting by participants.

Participant Feedback

Participants' questionnaires

A participants' satisfaction questionnaire is in progress, with results available in 2017.

Information to develop services has been gathered from:

- A combined questionnaire on patterns of practice in automated counting, development priorities for EQA and the laboratory diagnosis of anaemia. This questionnaire included the use of manual reticulocyte counting
- An evaluation questionnaire following the participants' meeting

Participant and SAG suggestions for improvement: This is now a standing item on the agenda of each Haematology staff meeting. Suggestions from participants and SAG members are automatically included in the Haematology Scheme's Quality Improvement Plan.

Complaints

A total of 12 complaints were received in 2016. In most cases, the classification as a complaint was the action of Scheme staff and not the request of the participant. 10/12 complaints were fully upheld, 2/12 partially upheld. 11/12 were responded to within the expected timeframe.

A full report of the complaints and quality incidents for 2016 was made to the Annual Quality Review.

Previous years' complaints totals were 9 (2015), 23 (2014), 24 (2013), 9 (2012), 9 (2010-2011), 9 (2009-2010), 12 (2008-2009) and 9 (2007-2008).

Publications, Communications and Education

Annual Participants' Symposium

The 19th Annual Participants' Symposium was held at Emirates Old Trafford Cricket Ground October 2016 with the theme of 'Quality Improvement: Reflecting Real Life'. 255 delegates attended. The programme included an extended session on 'Where Does the Responsibility for Quality Lie?'. Feedback on the meeting was good, with 95% of delegates marked the programme and venue as good or excellent.

The 2017 meeting will be held in at Manchester United Football Club in October.

Annual Report and Participants' Manual

The Annual report is available for download by participants from the UK NEQAS Haematology and Transfusion website. The most recent hard-copy version of the Participants' Manual (version 7) was distributed to all participants in 2016. Updated versions have been issued on-line..

Posters, publications and other presentations

Posters and short papers:

- ISLH 2016 (short paper on development of survey material for RDW/MPV, poster on the use of current survey material for RDW/MPV, poster on pre- and post-analytical surveillance)
- ACB Focus 2016 (poster on pre-and post-analytical surveillance)
- EQALM meeting (workshop participation on virtual microscopy and automated counting)

Invited speaker:

- ACB Focus 2016 (Presentation on pre- and post-Analytical Surveillance)
- AQMLM meeting March 2016 (Presentation on Adapting EQA to meet Participants' Needs)
- ISLH 2016 (Presentation on Critical Results Management on behalf of the ICSH)
- On-control Bone Marrow Biopsy workshop
- UK NEQAS Cellular Pathology Participants' Meeting (Presentation on UK NEQAS developments)
- Bio Rad User Group Meeting (Presentation on Standardisation in EQA)
- Teva Participants' Workshop (Various presentations on UK NEQAS Haematology)
- EuroBloodNet meeting (Presentation on EQA for Rare Haematological Disorders)

Publications

Ahmed L, Seal HL, Ainley C, De la Salle B, Hyde K, Burthem J and Gilmore W. *Web-Based Virtual Microscopy of Digitized Blood Slides for Malaria Diagnosis: An Effective Tool for Skills Assessment in Different Countries and Environments.* J Med Internet Res, 2016. **18**(8): p. e213.

De la Salle, B., Perry, D, *Quality Assurance*, in *Dacie and Lewis Practical Haematology*, B. Bain, Bates, I., Laffan M., Editor 2016, Elsevier.

Hinchliffe R.F., Mahon A, Thomas W, Dore CJ, Briggs C, De la Salle B, Hyde K. *Results of a prepilot study of potential test material for the external quality assessment of reticulocyte haemoglobin content.* International Journal of Laboratory Hematology, 2016. **38**(4): p. e86-e88.

Keng, T.B., De la Salle BJ, Bourner G, Merino A, Han JY, Kawai Y, Peng MT, McCafferty R. *Standardization of haematology critical results management in adults: an International Council for Standardization in Haematology, ICSH, survey and recommendations.* International Journal of Laboratory Hematology, 2016. **38**(5): p. 457-471.

Urassa W., N.M., De la Salle B., Bullock D., Tholen D., Burnett D., Cognat S., Best S., Hurlston M., Kalou M. and Carter J., *WHO manual for organizing a national external quality assessment programme for health laboratories and other testing sites*, 2016.