Blood Component Quality Monitoring Scheme

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Blood Component Quality Monitoring (CM)

UK NEQAS Haematology Participants' Manual

- Purpose
  - Supplement to the Full Blood Count Scheme
  - Designed for organisations that produce therapeutic blood products
- Analytes
  - Hb, Hct, PLT
- Specimens distributed
  - 2 Red Cells, 2 Platelet concentrate
- 4 distributions per year

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Blood Component Quality Monitoring (CM) Initial meeting

- 2005 Meeting between NBS and UK NEQAS (H)
  - NBS laboratories registered in UK NEQAS (H) FBC
  - FBC Scheme designed for Hospital laboratories
  - Haemoglobin and platelet counts at decision points for clinical use
  - NBS labs measuring at levels in Blood Components
    - Can exceed stated linearity of instrument

Blood Component Quality Monitoring (CM) Pilot Scheme

- 2005 – 2006 Pilot Scheme developed
  - Material developed
    - ‘Fresh’ Platelet pools & plasma reduced blood
    - Red Cells used for Haemoglobin
      - Concentration adjusted by centrifigation
    - Platelet pools concentrated by centrifigation
      - Counts adjusted by adding back supernatent
      - Platelets partially fixed.

Blood Component Quality Monitoring (CM)

- Specimens distributed
  - 2 Red Cells (Haemoglobin)
  - 2 Platelets
- Specimens analysed on same day
- Results returned to UK NEQAS (H)

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Blood Component Quality Monitoring (CM)
First pilot exercise

- 16 laboratories
  - 7 monitored instruments in two modes
  - 24 instruments
- Instrument identified by PRN in FB Scheme
- Mixture of instruments
  - Abbott, Beckman Coulter, Horiba, Siemens, Sysmex
- All methods statistics

Blood Component Quality Monitoring (CM)

- Statistical analysis
  - Non-parametric statistics
    - Median as target
- Outliers – agreed with NBS
  - Median ± 2% – Haemoglobin
  - Median ± 10% – Platelets

Reference

S. M. Lewis 2001 Quality Assurance. In: Dacie and Lewis Practical Haematology 9th edition, SM Lewis, BJ Bain and I Bates (eds), Churchill Livingstone.

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Blood Component Quality Monitoring (CM)

- 2007 Biomedical Excellence for Safer Transfusion (BEST) laboratories invited to take part in pilots
- 2008 Haematocrit added to tests
- 2009 Review meeting
  - NHSBT & UK NEQAS (H)
    - Performance reasonable
    - Immunoplatelet method for platelets in plasma
    - Work towards full scheme status

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Scoring

- 2013 Proposed Scoring
  - Data from 2010 – 2013
- Deviation Index
  - Chosen coefficient of variation (CCV)
  - Survey Standard Deviation (SD)

Scoring 2

- Deviation Index
  - Z-score
  - ISO13528
  - $z - score = \frac{(result - target)}{SD \text{ or } CCV}$
  - Consensus target (median)
  - SD = estimated SD
  - CCV = chosen coefficient of variation
- Discussed with Scheme Statistician
  - Use SD

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Interpretation of z-score

- From ISO13528

$|z| \leq 2.0$ acceptable

$2.0 \leq |z| \leq 3.0$ warning signal

$|z| \geq 3.0$ unacceptable (action signal)

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Scoring

- Scoring workup using data from 2013 – 2015
  - Scoring modelled on FBC Scheme
    - Absolute DI value taken
    - DI > 3.5 truncated to 3.5
    - Sum of last six DI values
    - Multiply by scaling constant (6)
    - Score
      - Score ≥ 100 – unsatisfactory performance

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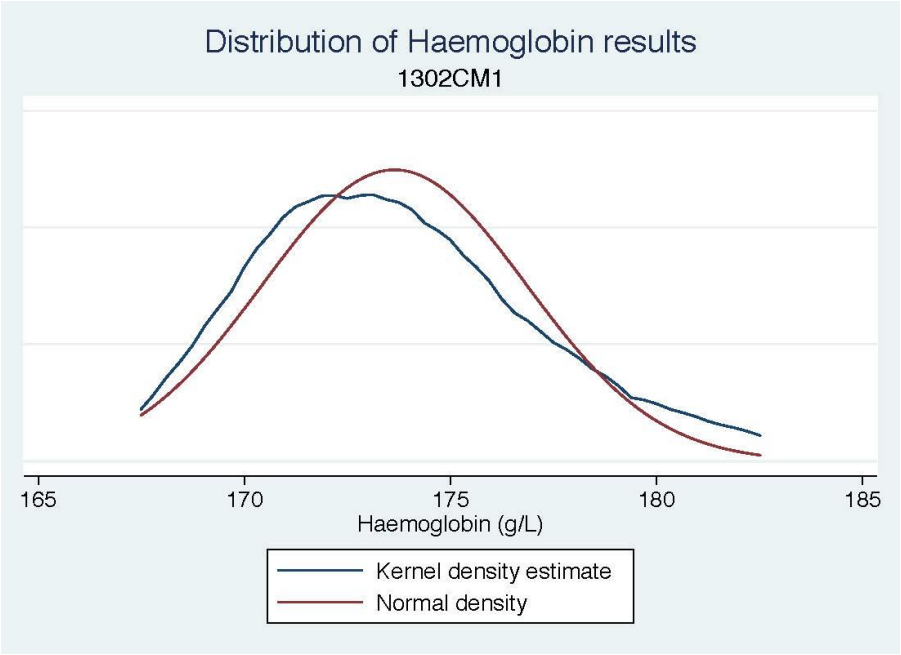
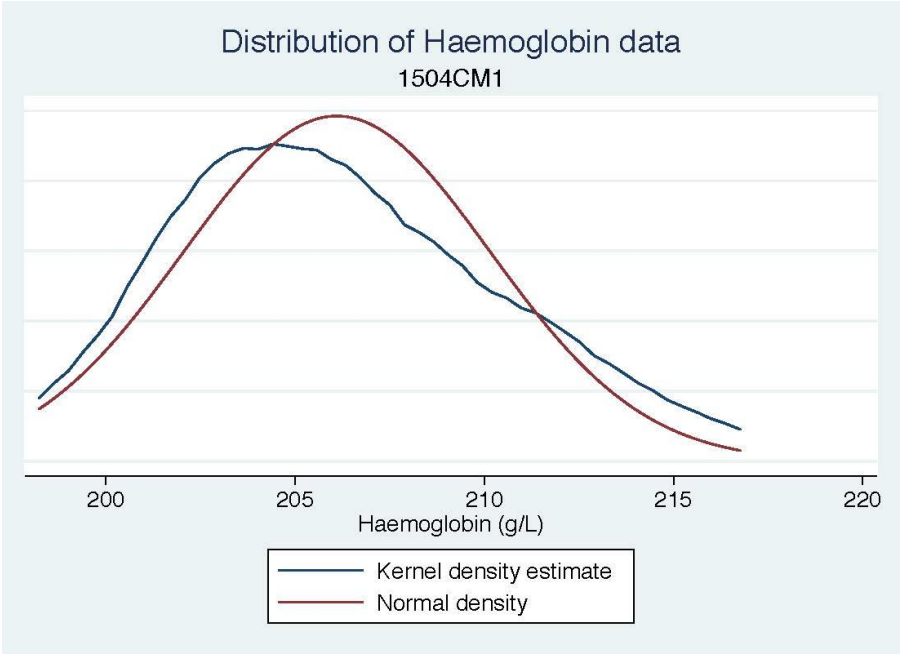
Haemoglobin Data





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UK Haemoglobin data

	Absolute & Truncated DI																					
Instrument	1302CM1	1302CM2	1303CM1	1303CM2	1304CM1	1304CM2	1401CM1	1401CM2	1402CM1	1402CM2	1403CM1	1403CM2	1404CM1	1404CM2	1501CM1	1501CM2	1502CM1	1502CM2	1503CM1	1503CM2	1504CM1	1504CM2
A	0.33725	0.5396	0	0	1.199111	0.469217	2.248333	0.852	2.248333	0.852	2.248333	0.852	0.65627	1.01175	1.0792	0.930345	1.055739	0.726385	1.01175	0.75293	0.33725	0.5396
B	1.349	0.8094	0	0	0.899333	0.469217	2.248333	1.42	2.248333	1.42	2.248333	1.42	0.947946	0.6745			1.290348	0.933923	0	0.125488	1.01175	0.8094
C	0.6745	0.2698	0.142	0.33725	0.899333	0	0.899333	0.568	0.899333	0.568	0.899333	0.568	0.364595	0.505875			0.82113	0.311308	0.843125	0.501953	0.505875	0.5396
D	0	0.5396	0.426	0.33725	0.899333	0.938435	0.449667	0.852	0.449667	0.852	0.449667	0.852	0.65627	0.33725			0.586522	0.726385	1.349	0.878419	0.6745	1.0792
E	1.68625	1.349	0.568	1.68625	0.599556	0.703826	0.449667	0.284	0.449667	0.284	0.449667	0.284	0.510432	0.505875	0	0	0.351913	0.518846	1.01175	0.75293	0.505875	1.349
F	1.01175	0.8094	0.994	1.68625	0.599556	0.469217	0	0.568	0	0.568	0	0.568	0.364595	0.505875	0	0	1.290348	0.726385	1.180375	0.627442	0.6745	0.5396
G	1.01175	0.8094	0.142	0.6745	0.299778	0.703826	0	0.284	0	0.284	0	0.284	0.218757	0.33725	0	0	1.055739	0.518846	1.349	0.75293	0.843125	1.0792
H	1.01175	1.0792	1.136	1.68625	0.599556	0.703826	1.798667	1.42	1.798667	1.42	1.798667	1.42	0.364595	0.505875	0	0	0.351913	0.518846	0.33725	1.380372	0.505875	0.2698
I	0.6745	0.5396	0.284	0.6745	0.299778	2.111478	1.798667	0.568	1.798667	0.568	1.798667	0.568	0.072919	0.6745	0.21584	0.372138	0.351913	0.726385	0.33725	0.250977	0	0.2698
J	0.33725	0	0.142	0.33725	0	0.469217	0.449667	0.284	0.449667	0.284	0.449667	0.284	0.072919	0.33725	0.43168	0.558207	0.351913	0.518846	0.33725	0.627442	0	0
K	0.33725	1.0792	3.5	0.6745	1.798667	2.111478	0	0	0	0	0	0	1.239622	0.505875	1.0792	0.930345	1.290348	1.349	0.168625	0.75293	1.68625	2.9678
L	1.68625	1.6188	0.568	0.33725	0.599556	0.234609	0	0.284	0	0.284	0	0.284	0.072919	0.168625								
M	0.33725	0	0	0	0.599556	0	0.449667	0	0.449667	0	0.449667	0	0.072919	0.505875	0.43168	0.372138	0.351913	0.103769	0.505875	0.125488	0	0
N	0.33725	0	0.284	0	0.599556	0.703826	0.449667	0.852	0.449667	0.852	0.449667	0.852	0.364595	0.505875	0.43168	0.744276	0.586522	0.311308	1.01175	0.376465	0	0
O	0.6745	1.349	0.71	1.349	0.599556	1.173043	1.349	1.704	1.349	1.704	1.349	1.704			1.0792	0.930345						
P	1.349	1.0792	0.568	1.68625	0.899333	0.469217	1.798667	0.852	1.798667	0.852	1.798667	0.852			0.43168	0.558207						
Q	0	0.5396	0.852	0.6745	0.899333	1.173043	0.899333	1.136	0.899333	1.136	0.899333	1.136	0.802108	0.843125			1.290348	1.349	1.349	0.878419	0.6745	0.8094
R	0.33725	0.2698	0.71	1.01175	1.199111	0.469217	0.449667	0.284	0.449667	0.284	0.449667	0.284							1.349	0.75293	0.6745	1.0792
S																	0.82113	0.311308			0.6745	1.0792
R																					0.33725	0.5396
U	0.6745	0	0	0.6745	0.599556	0.938435	0.899333	1.988	0.899333	1.988	0.899333	1.988	0.218757	0.33725	0.64752	0.558207	0.351913	0.311308	0	0.376465	0.33725	0.5396
V																					1.68625	1.8886
W	0.6745	0.2698	1.278	2.0235	0	0.938435	2.248333	0.852	2.248333	0.852	2.248333	0.852	0.072919	1.180375	3.02176	1.488552	0.117304	0.518846	1.180375	0.627442	1.349	1.349
X	0.6745	0.8094																				
Y			1.42	2.0235	0.599556	1.407652	1.349	2.556	1.349	2.556	1.349	2.556										

Key	
	< 1
1.5	> 1 < 2
2.5	> 2 < 3
3.5	> 3

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UK Haemoglobin data

	Scores								
Instrument	1304CM	1401CM	1402CM	1403CM	1404CM	1501CM	1502CM	1503CM	1504CM
A	15.27107	28.61197	47.21397	55.806	47.21212	40.66739	32.75813	33.33809	26.54192
B	21.1617	30.2213	52.2313	66.03	53.75468	53.75468	45.0903	23.83323	25.02546
C	13.9373	17.0755	23.004	26.412	22.83082	22.83082	20.82145	20.08792	21.13795
D	18.84371	23.41611	26.64661	23.43	21.58112	21.58112	21.64856	27.20307	31.76415
E	39.55729	25.74779	16.62429	13.206	14.90184	10.49984	11.3224	15.81264	26.94189
F	33.42104	25.90214	13.22864	10.224	12.03882	8.630818	17.32321	22.9473	30.2319
G	21.84752	12.62462	9.429623	5.112	6.744041	5.040041	12.78355	22.05909	33.59304
H	37.29949	44.06579	46.44429	57.936	43.84682	24.53482	10.44737	15.53029	20.18434
I	27.50314	34.41854	42.86754	42.6	32.88451	22.21238	14.48217	13.52701	11.61795
J	7.714304	10.0928	11.6193	13.206	11.26501	12.80233	13.62489	16.95203	11.01271
K	57.00657	48.50787	23.46087	0	10.47298	22.53025	38.36634	33.42269	49.28972
L	30.26679	12.14049	8.412986	5.112	4.857264	4.857264	4.857264	4.857264	4.857264
M	5.620833	6.295333	8.993333	8.094	8.868764	10.99367	11.02976	11.34518	6.522274
N	11.54779	17.33429	23.44029	23.43	20.84282	20.08855	17.66553	20.772	13.71627
O	35.13059	41.30759	47.27159	54.954	54.954	48.69327	48.69327	48.69327	48.69327
P	36.306	37.6408	40.0193	47.712	47.712	37.74732	37.74732	37.74732	37.74732
Q	24.83086	33.80526	36.85826	36.636	34.2954	34.2954	37.91949	39.072	38.104
R	23.98277	24.74247	18.81397	13.206	13.206	13.206	13.206	21.41558	27.53578
S							6.794629	6.794629	17.31683
R									5.2611
U	17.32194	30.59894	43.87594	51.972	37.98404	27.8944	14.54973	13.47248	11.49922
V									21.4491
W	31.10541	44.04161	42.83461	55.806	44.72376	49.36432	38.39854	41.72567	30.8518
X	8.9034	8.9034	8.9034	8.9034	8.9034	8.9034	8.9034	8.9034	8.9034
Y	32.70425	56.13425	58.90325	70.29	70.29	70.29	70.29	70.29	70.29

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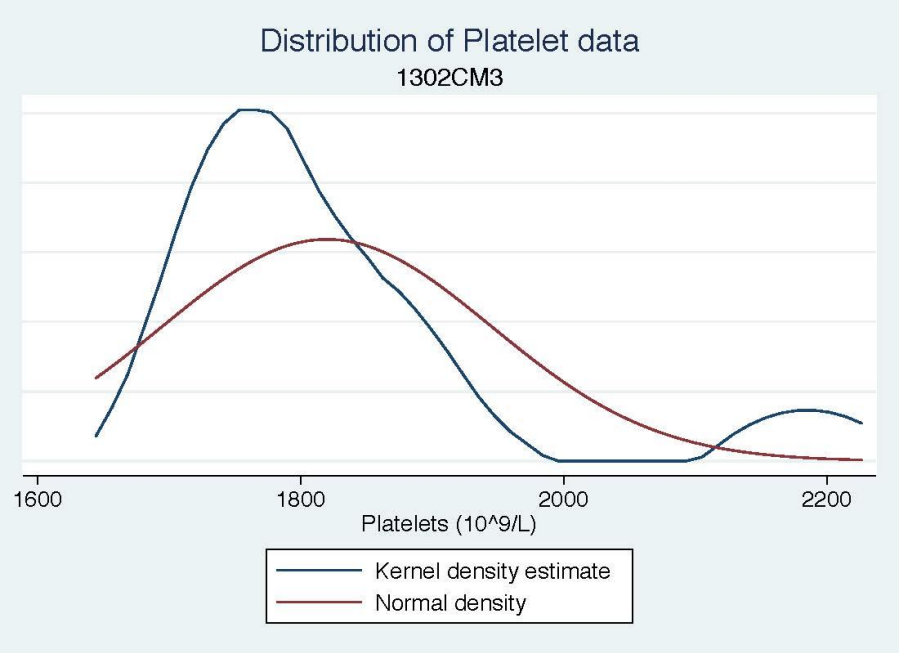
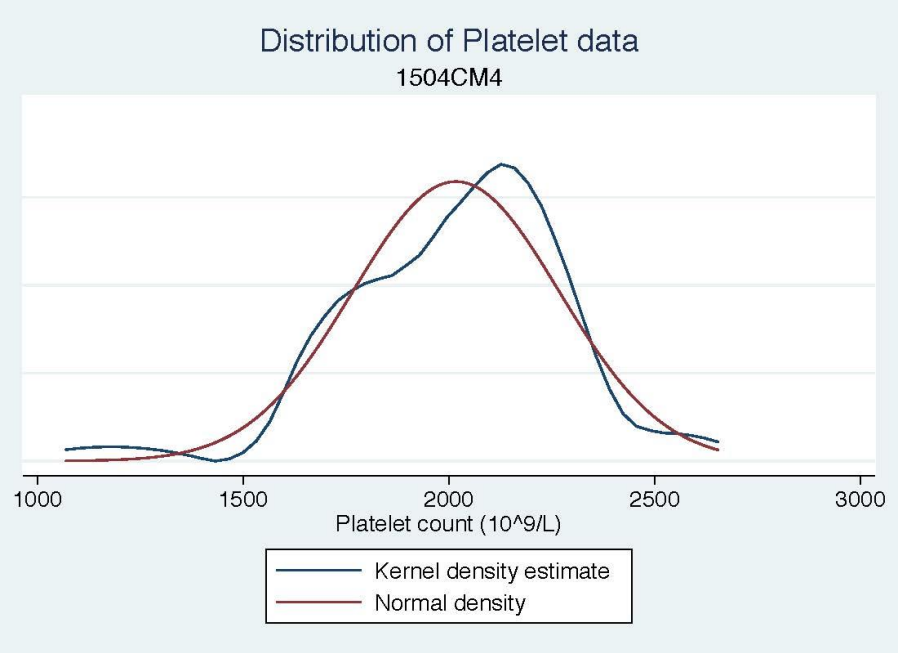
Platelet Data





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UK Platelet Data

	Absolute & Truncated DI																					
Instrumen	1302CM1	1302CM2	1303CM1	1303CM2	1304CM1	1304CM2	1401CM1	1401CM2	1402CM1	1402CM2	1403CM1	1403CM2	1404CM1	1404CM2	1501CM1	1501CM2	1502CM1	1502CM2	1503CM1	1503CM2	1504CM1	1504CM2
A	0.733667	0.075787	0.2485	0.284	0.750748	1.66802	0	0.195754	0	0.195754	0	0.195754	0.024527	0.277735	0.314429	0.260048	1.129741	0.277205	0.311813	0.082955	0.214651	0.580465
B	0.414167	0.39409	0.934833	0.441778	0.586522	0.556007	0.193561	0.400019	0.193561	0.400019	0.193561	0.400019	0.110373	0.886108			0.185813	0.224042	0.915745	2.832307	1.007209	0.664052
C	0.508833	0.136416	0.698167	0.142	1.173043	0.720074	0.244914	0.442574	0.244914	0.442574	0.244914	0.442574	0.735818	0.780304			0.401355	0.455679	0.108314	0.146158	0.994	0.589752
D	0.343167	0.212202	0.556167	0.063111	0.445757	0.720074	0.154059	0.306397	0.154059	0.306397	0.154059	0.306397	0.159427	0.105804			0.787846	0.250624	0.810713	2.042264	1.172326	0.622258
E	0.568	0.287989	3.5	1.025556	1.478035	1.358115	0.782143	0.127666	0.782143	0.127666	0.782143	0.127666	0.049055	0.330637	0	0	0.022298	1.374632	0.712246	0.643886	0.320326	0.501522
F	0	0.212202	0.769167	0.299778	2.181861	1.722709	1.196917	1.029836	1.196917	1.029836	1.196917	1.029836	0.367909	0.502569	0	0	1.241229	1.146792	0.640036	0.999406	0.696791	0.547959
G	0.662667	0.742708	0.863833	0.473333	0.093843	0.811223	1.106061	1.438366	1.106061	1.438366	1.106061	1.438366	1.115991	0.81998	0	0	0.096623	1.253118	0.65973	0.075054	1.278	0.752282
H	0.378667	0.106101	0.011833	1.735556	0.985357	1.139358	1.204817	1.727741	1.204817	1.727741	1.204817	1.727741	0.331118	0.608373	0	0	0.431085	1.051859	1.322742	0.628085	0.749628	0.891594
I	0.6035	0.424404	0.8875	0.899333	0.633443	0.483088	3.5	3.5	3.5	3.5	3.5	3.5	0.956564	0.462892	0.324571	0.541767	0.341895	0.125312	0.876358	1.275921	0.399581	0.111449
J	0.721833	0.621449	1.337167	1.246444	0.82113	0.428399	3.5	3.5	3.5	3.5	3.5	3.5	1.042409	0.26451	0.111571	0.736803	0.007433	0.064555	1.04047	1.884255	0.181628	0.018575
K	1.136	1.636989	2.0945	0.394444	2.909148	2.397209	0	0	0	0	0	0	0.171691	0.502569	0.781	3.5	0.364193	0.284799	0.370893	2.168671	0.716605	0.733707
L	0.8165	1.439944	1.857833	0.252444	0.070383	0.282561	0.912501	1.114946	0.912501	1.114946	0.912501	1.114946	1.447109	2.301235								
M	0.272167	0.212202	0.437833	0.362889	0.351913	0.173182	0.019751	0.110644	0.019751	0.110644	0.019751	0.110644	0.036791	0	0.669429	0.563438	1.025686	0.429098	0.246168	0.430574	0.855302	0.612971
N	0.355	0.045472	0.343167	0.347111	0.398835	0.519547	0.118507	0.331931	0.118507	0.331931	0.118507	0.331931	0	0.317412	0.547714	0.758474	1.650017	0.4253	0.554698	0.35947	0.888326	0.617614
O	0.153833	0	1.9525	0.820444	0.093843	0.519547	0.027652	0.527685	0.027652	0.527685	0.027652	0.527685			0.862143	0.390072						
P	0.71	0.970067	0.5325	0.063111	0.304991	0.009115	0.019751	0.042555	0.019751	0.042555	0.019751	0.042555			1.075143	0.086683						
Q	0.1775	0.666921	1.479167	1.388444	0.304991	0.009115	0.347619	0.297886	0.347619	0.297886	0.347619	0.297886	0.306591	0.568696			1.434474	0.535423	1.355564	2.105467	0.974186	0.808007
R	0.047333	0.136416	0.130167	0.473333	0.586522	0.136723	0.584633	0.49364	0.584633	0.49364	0.584633	0.49364							1.545934	1.836852	0.630744	0.840513
S																	0.364193	0.296191			0.90814	0.696558
R																					0.05614	0.552602
U	1.207	1.18227	0.437833	2.477111	0.398835	1.923236	0.308117	0.102132	0.308117	0.102132	0.308117	0.102132	3.249864	0.648049	1.257714	0.62845	2.735163	1.370835	0.449667	0.075054	0.947767	0.933387
V																					1.991302	1.555645
W	1.5265	0.712393	0.343167	0.915111	0.375374	1.431034	0.142208	0.076599	0.142208	0.076599	0.142208	0.076599	0.110373	1.110941	0.344857	0.30339	0.869603	0.045568	0.882922	0.485877	0.293907	0.534028
X	1.3845	2.167494																				
Y			1.195167	0.694222	2.627617	3.5	1.406278	1.217079	1.406278	1.217079	1.406278	1.217079										

Key	
	< 1
1.5	> 1 < 2
2.5	> 2 < 3
3.5	> 3

UK NEQAS

International Quality Expertise

UK Platelet Data

	Scores								
Instrumen	1304CM	1401CM	1402CM	1403CM	1404CM	1501CM	1502CM	1503CM	1504CM
A	22.56433	18.88213	16.86166	3.523571	4.162623	6.43496	13.70211	14.25714	15.58097
B	19.96438	18.67632	13.97813	10.68443	13.10184	13.10184	11.99949	30.92632	34.97501
C	20.2712	20.52463	19.60856	12.37478	17.34659	17.34659	18.36387	15.76577	16.17155
D	14.04287	13.47339	12.52046	8.288209	7.11686	7.11686	10.58494	24.94006	34.11618
E	49.30616	49.62909	27.93461	16.37656	13.19586	7.737005	10.65973	16.51837	21.44945
F	31.1143	43.2016	50.14845	40.08155	31.9439	18.58338	19.55099	24.16478	31.63327
G	21.88565	28.71996	35.96353	45.79969	42.14896	26.88239	19.71427	12.50715	24.68884
H	26.14123	40.82797	47.93899	52.78605	40.82764	23.23229	14.53461	20.60263	30.44996
I	23.58761	59.42019	90.69919	126	92.51673	55.71477	16.51801	20.91495	18.7831
J	31.05854	64.99884	91.49717	126	91.84151	54.93176	13.36368	23.07052	19.18149
K	63.40974	46.77181	31.83814	0	4.045557	29.73156	33.62551	44.81733	27.83321
L	28.31799	26.94401	26.44703	36.49405	46.81943	46.81943	46.81943	46.81943	46.81943
M	10.86112	8.737274	4.715308	2.347103	1.785481	8.400311	16.34665	20.18635	21.59879
N	12.05479	12.35458	10.91554	8.107869	7.309717	12.44422	22.1935	25.77404	26.97255
O	21.24101	23.65003	10.34438	9.996049	9.996049	14.17732	14.17732	14.17732	14.17732
P	15.53871	5.832142	2.632313	1.121513	1.121513	7.718629	7.718629	7.718629	7.718629
Q	24.15683	22.96334	9.630706	11.6191	12.99779	12.99779	20.94414	37.83729	43.27873
R	9.062963	14.43011	17.27874	19.40891	19.40891	19.40891	19.40891	33.23599	35.5939
S							3.962306	3.962306	13.59049
R									3.652452
U	45.75771	33.88359	18.85542	7.384493	28.31047	37.16596	59.34044	39.10129	39.07124
V									21.28169
W	31.82147	19.70096	13.46413	3.938531	9.953571	11.16947	16.70839	17.5933	18.67143
X	21.31197	21.31197	21.31197	21.31197	21.31197	21.31197	21.31197	21.31197	21.31197
Y	48.10204	63.84218	68.24599	47.22043	47.22043	47.22043	47.22043	47.22043	47.22043

UK NEQAS

International Quality Expertise

Review Meeting February 2016

- 25 participants
- 46 reporting methods
- 23 UK
- 23 Non-UK
- 9 countries
  - Finland, France, Gibraltar, Ireland, Italy, Kenya, The Netherlands, Portugal, UK
- Included in scope of accreditation for ISO17043

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What next?

- Develop a graphical report format
- Consider extending the closing date
- Shadow scoring
- Consider increasing number of distributions to 6 per year
- On-line data returns/reports

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