UK NEQAS
Leucocyte Immunophenotyping

Sheffield Teaching Hospitals NHS
NHS Foundation Trust

Measurable Residual Disease for Plasma Cell Myeloma Programme (not accredited) Sample 019

All Participant Report

Distribution – 212202 Participant -

Date Issued –08 September 2021 Closing Date – 28 September 2021 Machine Used -

Trial Comments

This trial was issued to 56 participants. This is the final version of the report.

Sample Comments

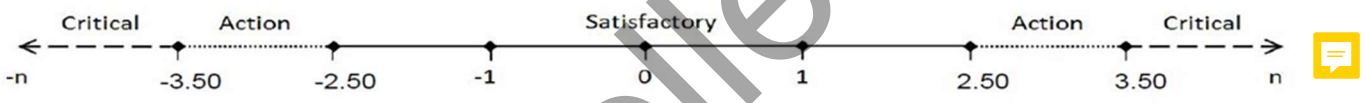
This sample was manufactured using a plasma cell myeloma sample and stabilised whole blood.

Results and Performance

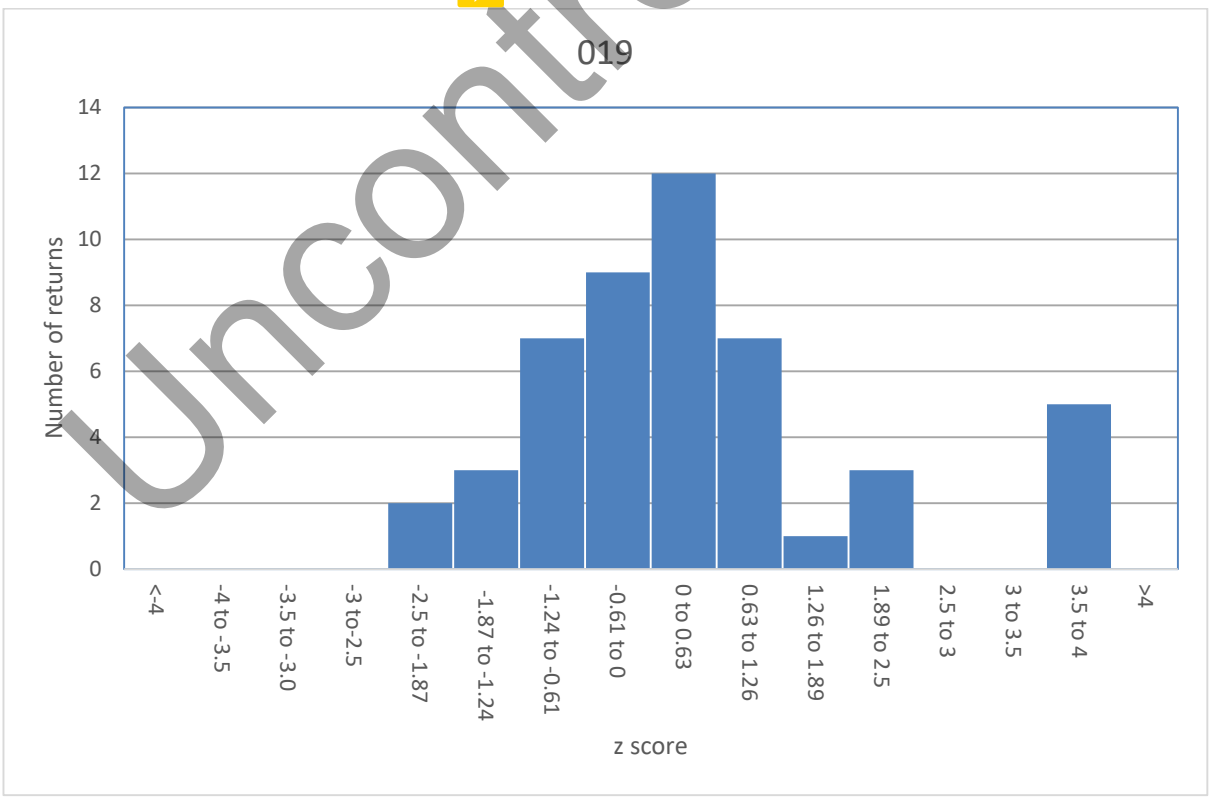
Percentage MRD Population	Your Results (%)	Robust Mean (%)	Robust SD (%)
		0.02	0.01

Percentage MRD Population	z Score *	Performance Status for this sample	Performance Status Classification Over 12 Sample Period		
			Satisfactory	Action	Critical

***z Score Limits Definitions - Please note the scale below is applicable to the tables above**



Histograms of Participant z Scores



Measurable Residual Disease for Plasma Cell Myeloma Programme (not accredited) Sample 020

All Participant Report

Distribution – 212202 Participant -

Date Issued – 08 September 2021 Closing Date – 28 September 2021 Machine Used -

Trial Comments

This trial was issued to 56 participants. This is the final version of the report.

Sample Comments

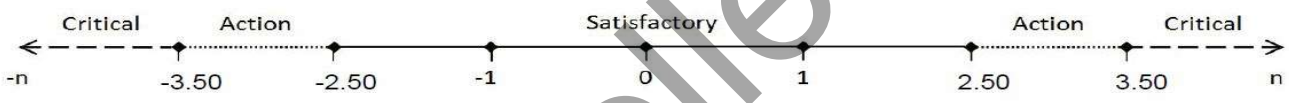
This sample was manufactured using a plasma cell myeloma sample and stabilised whole blood.

Results and Performance

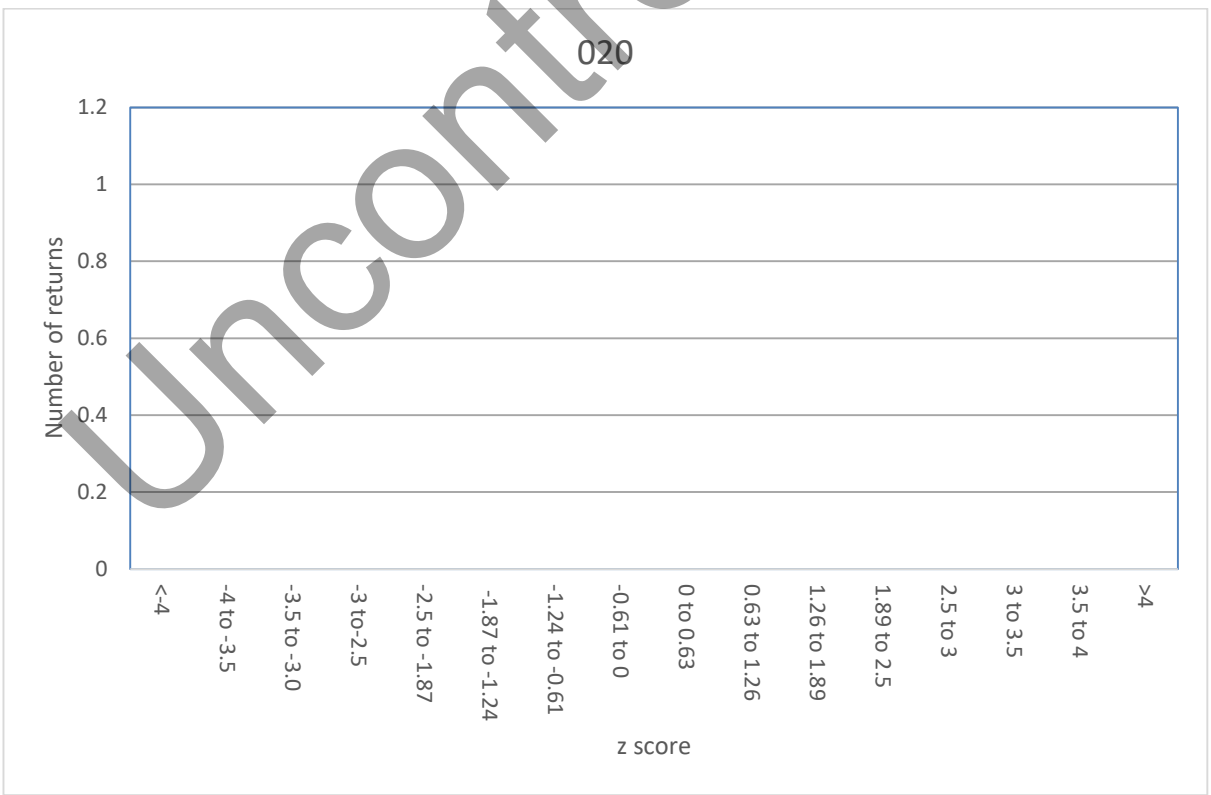
Percentage MRD Population	Your Results (%)	Robust Mean (%)	Robust SD (%)
		0.00	0.00

Percentage MRD Population	z Score *	Performance Status for this sample	Performance Status Classification Over 12 Sample Period		
			Satisfactory	Action	Critical

***z Score Limits Definitions – Please note the scale is applicable to the tables above.**



Histograms of Participant z Scores



Flow Cytometer used

Flow Cytometer	Returns (n=48)
BD FACSCanto II	17
BD FACSLyric	16
BD FacsVerse	1
BD LSR II	1
BD LSR Fortessa	2
Coulter Navios	7
Coulter Gallios	1
Cytognos Omnicyte	1
Coulter DxFLEX	2

Antibody Usage

Antibody	Number of Users (n=49)
B2 Microglobulin	5
VS38c	2
CD19	47
CD20	11
CD27	38
CD28	8
CD38	48
CD45	46
CD56	48
CD81	35
CD117	37
CD138	49
CD200	6
IgG Kappa	38
IgG Lambda	38

Reported Staining Intensity (numbers differ from antibody usage table as not all centres submitted full results)

Antibody	Absent		Moderate		Strong		Total
	%	n	%	n	%	n	
B2 Microglobulin	0	0	0	0	100	5	5
VS38c	50.0	1	0	0	50.0	1	2
CD19	84.8	39	13.0	6	2.2	1	46
CD20	70.0	7	20.0	2	10.0	1	10
CD27	42.1	16	42.1	16	15.8	6	38
CD28	14.2	1	42.9	3	42.9	3	7
CD38	0	0	23.4	11	76.6	36	47
CD45	11.4	5	72.7	32	15.9	7	44
CD56	27.0	13	54.2	26	18.8	9	48
CD81	47.2	17	38.9	14	13.9	5	36
CD117	59.4	19	34.4	11	6.2	2	32
CD138	0	0	17.8	8	82.2	37	45
CD200	50.0	3	33.3	2	16.7	1	6
IgG Kappa	12.1	4	48.5	16	39.4	13	33
IgG Lambda	82.9	29	11.4	4	5.7	2	35

Conclusion

A total of 15 markers are routinely being used and 25 different panels, compared to 20 panels for the previous exercise. There was good consensus with core markers of CD138, CD38, CD19, CD45 and CD56 being common to most panels and many panels also containing CD27, CD81 and CD117. The most popular panel (n=15) again being: CD138, CD38, CD56, CD19, CD45, CD27, CD117, CD81 IgG kappa and IgG lambda.

	Antigen Panel															n=
1	CD138	CD38	CD56	CD19	CD45	CD27	CD117	CD81	Igκ	Igλ		CD28	CD200			2
2	CD138	CD38	CD56	CD19	CD45	CD27	CD117	CD81	Igκ	Igλ		CD28		B2M		3
3	CD138	CD38	CD56	CD19	CD45	CD27	CD117	CD81	Igκ	Igλ	CD20					1
4	CD138	CD38	CD56	CD19		CD27	CD117	CD81	Igκ	Igλ						1
5	CD138	CD38	CD56	CD19	CD45	CD27	CD117	CD81	Igκ	Igλ						15
6	CD138	CD38	CD56	CD19		CD27	CD117	CD81	Igκ	Igλ	CD20					1
7	CD138	CD38	CD56	CD19	CD45			CD81	Igκ	Igλ	CD20					1
8	CD138	CD38	CD56	CD19	CD45	CD27		CD81	Igκ	Igλ					VS38c	1
9	CD138	CD38	CD56	CD19	CD45	CD27		CD81	Igκ	Igλ		CD28				1
10	CD138	CD38	CD56	CD19	CD45	CD27	CD117		Igκ	Igλ	CD20					1
11	CD138	CD38	CD56	CD19	CD45	CD27	CD117		Igκ	Igλ	CD20	CD28				1
12	CD138	CD38	CD56	CD19	CD45		CD117		Igκ	Igλ						1
13	CD138	CD38	CD56	CD19	CD45	CD27	CD117		Igκ	Igλ						1
14	CD138	CD38	CD56	CD19	CD45	CD27			Igκ	Igλ						2
15	CD138	CD38	CD56	CD19	CD45				Igκ	Igλ	CD20					2
16	CD138	CD38	CD56	CD19	CD45				Igκ	Igλ				B2M		2
17	CD138	CD38	CD56	CD19	CD45				Igκ	Igλ						1
18	CD138								Igκ	Igλ					VS38c	1
19	CD138	CD38	CD56	CD19	CD45	CD27	CD117	CD81			CD20		CD200			2
20	CD138	CD38	CD56	CD19	CD45	CD27	CD117	CD81					CD200			1
21	CD138	CD38	CD56	CD19	CD45	CD27	CD117	CD81				CD28	CD200			1
22	CD138	CD38	CD56	CD19	CD45	CD27	CD117	CD81								3
23	CD138	CD38	CD56	CD19	CD45		CD117	CD81			CD20					2
24	CD138	CD38	CD56		CD45	CD27	CD117									1
25	CD138	CD38	CD56	CD19	CD45											1

Sample 019 was manufactured to contain 0.01% neoplastic plasma cells and consensus values returned reflected this. Based upon participants in house criteria the consensus for sample 019 was MRD present. Three participants considered that the sample would be recorded as MRD absent (0% 0.01% and 0.01%) and one stated that it would be recorded as below their LLOQ. Recorded total number of events acquired for this sample ranged from 2000 to 3093975 and number neoplastic plasma cell events ranged from 0 to 1380.

Sample 020 was designed to contain neoplastic plasma cells at a level of 0.001% and 3 centres were able to obtain enough events to justify this limit of detection. Consensus was MRD Absent (30/47). 17 centres reported MRD Present (range 0.001% to 0.117%) although 5 of these observed fewer than 15 neoplastic events. The recorded total number of events acquired for this sample ranged from 112010 through to 2935538. The number of neoplastic events ranged from 0 to 381. Please note that this sample is not being performance monitored.

Information with respect to compliance with standards BS EN ISO/IEC 17043:2010

4.8.2 a) The proficiency testing provider for this programme is:
UK NEQAS for Leucocyte Immunophenotyping
Pegasus House, 4th Floor Suite
463A Glossop Road
Sheffield, S10 2QD
United Kingdom
Tel: +44 (0) 114 267 3600, Fax: +44 (0) 114 267 3601
e-mail: amanda.newbould@ukneqasli.co.uk

4.8.2 b) The coordinators of UK NEQAS LI programmes are Mr Liam Whitby (Director) and Mr Stuart Scott (Centre Manager).

4.8.2 c) Person(s) authorizing this report:
Mr Liam Whitby (Director) or Mr Stuart Scott (Centre Manager) of UK NEQAS LI.

4.8.2 d) No activities in relation to this EQA exercise were subcontracted.

4.8.2 g) The UK NEQAS LI Confidentiality Policy can be found in the Quality Manual which is available by contacting the UK NEQAS LI office. Participant details, their results and their performance data remain confidential unless revealed to the relevant NQAAP when a UK participant is identified as having performance issues.

4.8.2 i) All EQA samples are prepared in accordance with strict Standard Operational Procedures by trained personnel proven to ensure homogeneity and stability. Where appropriate/possible EQA samples are tested prior to issue. Where the sample(s) issued is stabilised blood or platelets, pre and post stability testing will have proved sample suitability prior to issue.

4.8.2 l), n), o), r) & s) Please refer to the UK NEQAS LI website at www.ukneqasli.co.uk for detailed information on each programme including the scoring systems applied to assess performance (for BS EN ISO/IEC 17043:2010 accredited programmes only). Where a scoring system refers to the 'consensus result' this means the result reported by the majority of participants for that trial issue. Advice on the interpretation of statistical analyses and the criteria on which performance is measured is also given. Please note that where different methods/procedures are used by different groups of participants these may be displayed within your report, but the same scoring system is applied to all participants irrespective of method/procedure used.

4.8.2 m) We do not assign values against reference materials or calibrants.

4.8.2 q) Details of the programme designs as authorized by The Steering Committee and Specialist Advisory Group can be found on our website at www.ukneqasli.co.uk. The proposed trial issue schedule for each programme is also available.

4.8.2 t) If you would like to discuss the outcomes of this trial issue, please contact UK NEQAS LI using the contact details provided. Alternatively, if you are unhappy with your performance classification for this trial, please find the appeals procedure at www.ukneqasli.co.uk/contact-us/appeals-and-complaints/