

Bowel Screening:
Scottish Bowel Screening Programme

Quality in Faecal Immunochemical Testing – What to monitor, what to control

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Measurement of variation within an analytical system

- ▶ **Pre-analytical** – must be cognisant of and monitor
 - ▶ Biological
 - ▶ Sampling
 - ▶ Handling of sample by participant and at specimen reception
- ▶ **Analytical** – we can control and improve
 - ▶ Reagent preparation
 - ▶ Calibration and control
 - ▶ External quality assessment

Pre-analytical variation: developmental stage of lesion, morphological characteristics

Timescale 2 – 5 years → 2 – 5 years

normal → low risk adenoma → high risk adenoma → cancer

Pre-analytical variation: transit time, stool consistency and volume of sample

Bristol Stool Chart

Type 1	Separate hard lumps, like nuts (hard to pass)
Type 2	Sausage-shaped but lumpy
Type 3	Like a sausage but with cracks on its surface
Type 4	Like a sausage or snake, smooth and soft
Type 5	Soft blobs with clear-cut edges (passed easily)
Type 6	Puffy pieces with ragged edges, a mushy stool
Type 7	Watery to solid pieces. Entirely liquid

Pre-analytical variation: time taken to test and ambient temperature

SAMPLES AT 4° C SAMPLES AT 26° C

Analytical variation: reagent preparation

Sample size (high)	20	Sample size (low)	20
Lowest value	82.8	Lowest value	106.9
Highest value	126.8	Highest value	114.6
Arithmetic mean	106.12	Arithmetic mean	109.656
95% CI	101.20 to 111.05	95% CI	106.81 to 110.49
Variance	110.3	Variance	1.2
Standard deviation	10.5	Standard deviation	1.1
Sample size (low)	20	Sample size (high)	20
Lowest value	92.4	Lowest value	24.7
Highest value	90	Highest value	30.1
Arithmetic mean	86.655	Arithmetic mean	25.865
95% CI	85.6 to 27.59	95% CI	23.24 to 28.44
Variance	8.4	Variance	1.6
Standard deviation	2.9	Standard deviation	1.2

Analytical variation: calibration and control

Date start	Date finish	Lot	OC	n	Mean ng/ml	SD ng/ml	CV %	n	Mean ng/ml	SD ng/ml	CV %
06/07	27/08	01001	1	38	154.7	8.35	5.41	38	637.1	31.81	4.99
30/08	29/10	01001	1	74	150.7	5.87	3.90	74	620.9	23.06	3.71
01/11	08/11	08001	1	10	147.9	2.47	1.67	10	642.3	19.32	3.01
13/11	01/12	08001	1	22	153.6	5.23	3.41	21	640.9	20.73	3.23
03/12	23/12	08001	1	23	146.0	5.01	3.43	23	598.8	22.29	3.72
24/12	30/12	09013	1	5	162.2	5.85	3.61	5	682.8	13.21	1.94
06/01	11/01	09013	1	7	155.7	3.15	2.02	8	676.0	24.17	3.58
12/01	12/04	09013	1	53	158.8	13.43	8.46	54	672.1	35.61	5.33
12/07	27/08	01001	2	61	153.0	15.21	9.94	61	622.3	27.49	4.42
31/08	29/10	01001	2	72	153.2	4.73	3.09	72	614.5	20.36	3.31
01/11	08/11	08001	2	9	151.2	3.53	2.33	9	610.8	24.49	4.01
09/11	26/11	08001	2	21	155.8	4.83	3.01	20	619.4	21.90	3.54
03/12	23/12	08001	2	26	152.0	5.36	3.53	26	636.7	37.33	5.86
24/12	30/12	09013	2	3	155.7	19.63	12.31	3	658.3	70.50	10.51
06/01	11/01	09013	2	7	160.7	3.95	2.46	7	702.6	11.90	1.56
12/01	11/04	09013	2	59	158.7	15.95	9.98	59	653.8	25.99	3.89

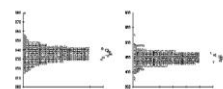
Analytical variation: calibration and control

Date start	Date finish	Lot	OC	n	Mean ng/ml	SD ng/ml	CV %	n	Mean ng/ml	SD ng/ml	CV %
06/07	29/10	01001	1	106	152.4	6.5	4.3	106	627.7	25.9	4.1
01/11	23/12	08001	1	48	150.7	5.6	3.7	47	630.9	24.2	4.2
24/12	12/04	09013	1	52	160.5	5.1	3.2	62	672.5	24.4	3.6
12/07	29/10	01001	2	130	152.4	4.6	3.0	130	617.9	20.0	3.2
01/11	23/12	08001	2	54	153.6	4.8	3.2	54	625.5	27.5	4.4
24/12	11/04	09013	2	54	162.6	6.0	3.7	53	697.3	20.8	3.0
Assigned		01001			156	6		627	27		
Assigned		08001			154	5		626	25		
Assigned		09013			161	7		685	20		
Overall (weighted)			1	204			3.9	215			4.0
Overall (weighted)			2	238			3.2	237			3.5
Overall (weighted)			1+2	444			3.5	452			3.8

Analytical variation: external quality assessment

2010 EQCS-OC

Thank you for taking part in this year's quality assessment programme.
Your results are detailed below.

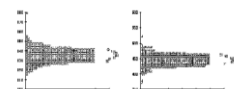


Sample A	Sample B
Lot ID: 005	Lot ID: 005
Mean value: 135.5	Mean value: 145.5
SD: 1.7	SD: 14.2
Min value: 114	Min value: 130
Max value: 160	Max value: 151

Analysed: SN N90417 (OC Diana 1)
Sample A: 131
Sample B: 421

2010 EQCS-OC

Thank you for taking part in this year's quality assessment programme.
Your results are detailed below.



Sample A	Sample B
Lot ID: 005	Lot ID: 005
Mean value: 135.5	Mean value: 145.5
SD: 1.7	SD: 14.2
Min value: 114	Min value: 130
Max value: 160	Max value: 151

Analysed: SN N90429 (OC Diana 2)
Sample A: 138
Sample B: 424

Conclusions

- ▶ **Pre-analytical variation** – no control of these areas, awareness and inclusion in setting analytical performance goals
- ▶ **Analytical variation** – can be measured, reviewed and manipulated to reduce bias within the system
- ▶ Overall control of the system requires multifaceted approach to ensure each component part operates within set analytical quality specifications
- ▶ This is evidenced by satisfactory performance in External Quality Assessment Scheme