

Appendix O. Laboratory Quality Control

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O.1. Serum transferrin receptor assay

Quality control samples (low, high) supplied by the kit manufacturer were run in each batch, as well as an unassayed human serum sample (Quality Assurance (QA) sample, used for consistency checking). The controls were assayed at the beginning and end of each batch and these statistics represented a combination of intra- and inter-assay precision. Results were checked to ensure they fell within the manufacturer's target range. Because the manufacturer's controls are different for each batch of kits, and three kit batches were used for assay runs which included DNSIYC samples, when only these runs are considered there were only sufficient data for statistics on the QA sample.

DNSIYC runs only:

	QA
mean (µg/ml)	8.15
sd (µg/ml)	0.43
n	42
cv (%)	5.24

Full year's quality control data for serum transferrin receptors:

	normal-65	high-65	normal-66	high-66	normal-67	high-67	QA
mean (µg/ml)	4.9	16.7	4.5	18.3	4.6	20.7	8.1
sd (µg/ml)	0.6	1.4	0.4	1.5	0.5	3.0	0.6
n	28	28	26	26	18	18	76
cv (%)	13.1	8.5	8.8	8.0	10.6	14.3	6.9

There is no external quality assessment scheme for serum transferrin receptor measurement.

O.2. Ferritin

Batch-to batch precision is monitored and assessed using internal quality control samples included in each run. Results for these samples were compared with the acceptable range before the results were accepted.

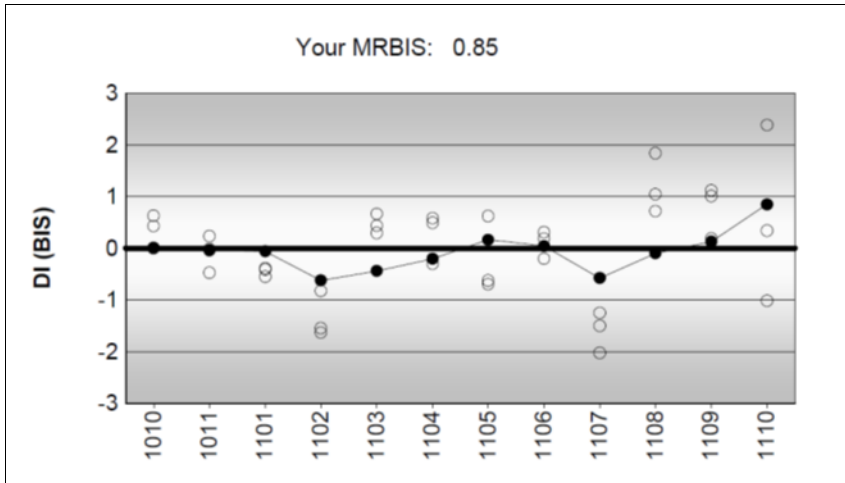
The following results were obtained for the batches which included DNSIYC samples:

	Lyphocek 1 40231	Lyphocek 2 40232	Lyphocek 3 40233
mean ($\mu\text{g/l}$)	62.1	159.6	382.7
sd ($\mu\text{g/l}$)	5.6	8.7	30.3
n	13	12	12
cv (%)	9.0	5.5	7.9

QC data for the full year for ferritin:

	Lyphocek 1 40241	Lyphocek 2 40242	Lyphocek 3 40243	Lyphocek 1 40231	Lyphocek 2 40232	Lyphocek 3 40233
mean ($\mu\text{g/l}$)	65.7	140.2	340.2	66.8	156.7	366.8
sd ($\mu\text{g/l}$)	2.0	7.9	9.2	7.4	10.1	30.4
n	25	27	27	51	50	50
cv (%)	3.1	5.7	2.7	11.0	6.5	8.3

Accuracy is assessed through membership of NEQAS in which our results for samples assayed "blind" are compared with target values and with results obtained in a large number of laboratories nationally. Laboratories are assessed on MRBIS (mean rolling bias index score) which should be as close as possible to 0. The plot below shows BIS (bias index score) against time (October 2010 to October 2011). The solid circles represent our performance and the open circles results by our method in other labs. This demonstrates a consistently high standard.



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O.3. Serum 25-hydroxyvitamin D (25-OHD)

The QC samples provided by DiaSorin were included in each run and the results were inspected to check that they were within the manufacturer’s acceptable limits. These QC samples are changed frequently by the manufacturer and therefore although they indicate that individual runs were within specification they do not give a view of long-term assay stability; therefore in-house unassayed controls were also used to monitor this.

Internal quality controls for 25-OHD

In-house control:

	full year	DNSIYC runs
mean (nmol/l)	55.9	54.8
sd (nmol/l)	6.6	3.1
n	42	11
cv (%)	11.9	5.7

Manufacturer’s controls (note that n is small):

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mean (nmol/l)	41.6	146.2	41.0	133.2	40.6	130.4
sd (nmol/l)	3.4	7.8	3.2	9.3	4.4	8.8
n	16	16	23	23	18	18
cv (%)	8.3	5.3	7.7	7.0	10.9	6.7

External quality controls for 25-OHD.

HNR subscribes to the DEQAS external quality assessment scheme and the results were within the target concentration range. The scheme does not provide cumulative performance data.

O.4. C-reactive protein

QC results for runs which included DNSIYC samples:

	Seronorm 1	Seronorm 2
mean (mg/l)	16.3	78.0
sd (mg/l)	0.3	2.4
n	13	24
cv (%)	1.7	3.1

Full year QC data 2010-11

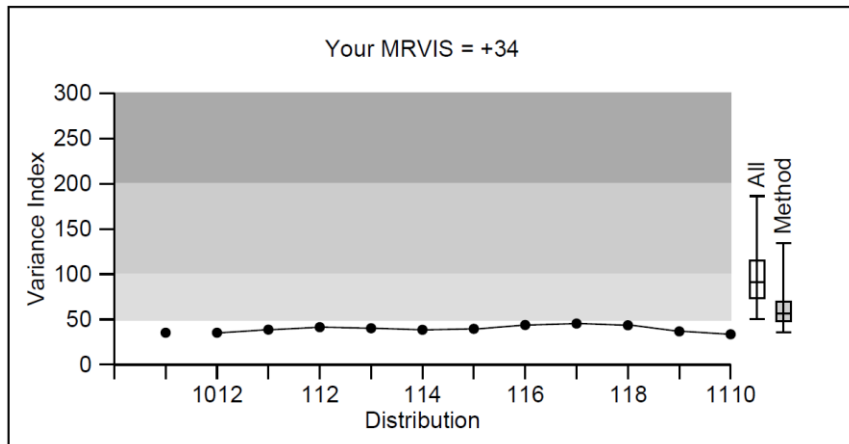
	Seronorm 1	Seronorm 2
mean (mg/l)	16.4	77.5
sd (mg/l)	0.4	2.2
n	39	103
cv (%)	2.3	2.8

External QC for C-reactive protein

NEQAS calculate and plot variance index and classify long-term performance on the basis of MRVIS (mean running variance index score). The score should be as low as possible – the white area 0 to 50 in the plot below represents best performance. This plot

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shows HNR NBA's variance index from October 2010 to October 2011, during which time DNSIYC samples were assayed, demonstrating consistently excellent performance.



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