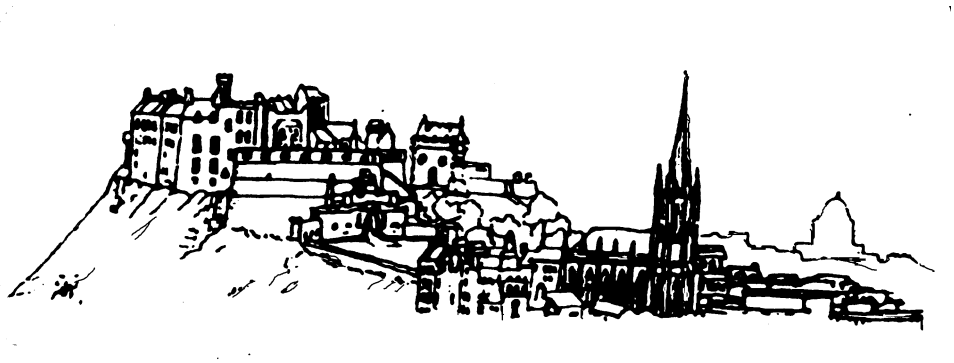
UK NEQAS

for

Peptide Hormones and Related Substances

Participants' Handbook

August 2018



UK NEQAS [Edinburgh]
Department of Laboratory Medicine
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Contents

1. Service provided

Scheme	Analytes
Peptide hormones I	Follicle stimulating hormone (FSH) Luteinising hormone (LH) Prolactin (PRL) and macroprolactin (pilot) Growth hormone (hGH) Anti-Müllerian Hormone (AMH)
Peptide hormones II	Parathyroid hormone (PTH) Adrenocorticotrophic hormone (ACTH) Calcitonin (hCT)
Tumour markers	Alpha-fetoprotein (AFP) Carcinoembryonic antigen (CEA) Chorionic gonadotrophin (hCG)
Maternal serum screening	Down's syndrome (1st trimester) Free β-subunit of hCG (hCGβ). PAPP-A Down's syndrome (1st trimester) Dried blood spots (Pilot) Placental growth factor (PLGF) (Pilot) Down's syndrome (2nd trimester) Alpha-fetoprotein (AFP): Chorionic gonadotrophin (hCG): Intact hCG, total hCG and the free β-subunit (hCGβ). Unconjugated oestriol (UE3) Inhibin A Neural tube defects Alpha-fetoprotein (AFP)
Pregnancy testing	Urinary hCG (qualitative) Urinary hCG (quantitative)
Placental growth factor (Pilot)	Placental growth factor (PLGF) (Pilot)
Liver fibrosis markers (Pilot)	Procollagen III amino terminal peptide (PIIINP) Hyaluronic acid Tissue inhibitor of metalloproteinase 1 (TIMP-1) Enhanced liver fibrosis (ELF) score Other liver fibrosis scores

The UK National External Quality Assessment Service (UK NEQAS) for Peptide Hormones and Related Substances [UK NEQAS [Edinburgh]] is part of a network of UK NEQAS Centres providing External Quality Assessment (EQA) for hormones and tumour markers. UK NEQAS [Edinburgh] collaborates closely with related UK NEQAS centres in Birmingham, Glasgow, Guildford and Sheffield.

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4. Service objectives

UK NEQAS [Edinburgh] aims to provide

- Professionally-led and scientifically-based EQA schemes with a primarily educational objective.
- Regular distributions of appropriately constituted specimens.
- Rapid feedback of individual participant performance in reports that are comprehensive and readily understood.
- Data on method-related performance.

The UK NEQAS [Edinburgh] laboratory is located within the Department of Laboratory Medicine, Royal Infirmary of Edinburgh, and there is a close working relationship between UK NEQAS and the Department.

UK NEQAS [Edinburgh] may sub-contract some services where appropriate.

5. Service accreditation

All schemes provided by UK NEQAS [Edinburgh] are currently accredited by the United Kingdom Accreditation Service [UKAS Reference No 8505]. The next on-site inspection will take place in September 2018.

Further information about standards for the accreditation of EQA schemes may be obtained from UKAS. (see Appendix 4 for contact details).

6. Enrolment procedures

Intending participants can access registration forms and other information on the UK NEQAS [Edinburgh] website (www.edqas.org) or can contact the unit to request these. Relevant documents include:

- Registration forms
- Participants' handbook
- Distribution schedule

Participation begins at the first distribution following receipt of completed registration forms. Enrolment may take place at any time of the year.

The majority of participants are UK NHS clinical service laboratories, but all laboratories - including non-UK, research and IVD manufacturers' laboratories - are most welcome to participate.

All UK clinical service laboratories must agree to theJoint Working Group (JWG) Conditions of Participation (Appendix 1).

Participation of non-UK laboratories may be subject to the availability of suitable specimen transport.

Manufacturers are welcome to participate fully in the same way as clinical service laboratories (receiving samples and returning results) or on an 'information only' basis. They may also register methods under development on an anonymous basis.

7. Charges and charging period

The financial year is from 1st April to 31st March, with a price list prepared annually and available on request. Participants will be advised of each year's charges in advance. Participation is deemed to be continuous so participants do not need to renew their subscription annually. Participation may begin at any time during the year. Charges for participation for part of the year are generally *pro rata*. Refunds of subscription charges are only payable under exceptional circumstances.

8. Service organisation

8.1 Laboratory Code Numbers

Each participant is assigned a unique code number, which is common to most UK NEQAS schemes. A participant may be assigned more than one code number if more than one instrument or method is in use for a single analyte. This will occur, for example, if a participant wishes to submit results for a method under evaluation as well as an established method. Second and subsequent registrations may be free of charge.

Please quote your laboratory code number in all communications including in the subject line of any e-mails.

8.2 Method codes

Methods are normally referred to by full name, but may occasionally be abbreviated.

Please check your method/code in all communications and inform us of any changes.

Manufacturers should note that in the interests of commercial confidentiality, a method under development can be temporarily assigned a "Method development" code until its general release, when it will be assigned an appropriate permanent code.

8.3 Confidentiality

The fact of participation, raw data, performance scores and all reports generated by UK NEQAS [Edinburgh] are confidential between the individual laboratory and UK NEQAS staff. Performance scores (and some relevant raw data) may be shared with the relevant Advisory Panel under defined circumstances (Appendix 1) as part of the routine reporting of persistent poor performance. Reports may also be shared by participants with local management, regional QA officers, accrediting bodies, and suppliers of equipment and reagents if they wish. Where appropriate and necessary, UK NEQAS staff may also divulge the information but only with the participant's written permission. Any other use must be approved by the UK NEQAS Scheme Director in advance.

9. Service operation

9.1 Specimens

All serum, plasma and urine specimens are of human origin. Specimens may be "spiked" with standards or other sources of analyte to give appropriate concentrations. Specimens are stored below -25°C prior to issue. During pool preparation, sera are clarified by membrane filtration (0.2 μm) and ProClin™ 200 (0.5% v/v) is added as a bacteriocide. Preservative is not added to lyophilised pools (Peptide II scheme). Urine specimens for the Pregnancy Testing scheme are not filtered but contain added ProClin™. The volume provided is 0.5-1.0 mL per specimen, depending on the analyte. Specimens are dispatched at ambient temperature. Specimen homogeneity is assessed prior to issue.

9.2 Safety precautions in handling specimens

Most pools are prepared from donations that have been individually confirmed to be negative for antibodies to human immunodeficiency virus (HIV), hepatitis B surface antigen (HBsAg) and antibodies to hepatitis C virus (HCV).

However, EQA specimens should always be handled with the same precautions that are normally adopted in the handling of patient specimens.

If it is not possible to test individual donations, one of the following alternative procedures may be adopted

a) The material may be virologically tested in pools of no more than twenty individual donations.
b) Material may be issued untested (participants are always made aware of this).

9.3 Schedule of specimen distribution

Specimens are distributed by first class post every 4 weeks (8 weeks for the Peptide II scheme), together with a results sheet. Electronic copies of the reports on the previous distribution are available to all participants. In addition, printed copies are sent to those who request them. Express mail or courier delivery is available to overseas participants at additional cost. Several analytes share specimens, as indicated below. The Distribution Schedule is on the scheme website at www.edqas.org.

Combinations of analytes and number of specimens per distribution.

Scheme	Analyte(s)	Specimens per Distribution	Distributions per annum
Peptide I	FSH, LH, AMH, prolactin Growth hormone	5 4	12
Peptide II	PTH ACTH Calcitonin	4 3 3	6
AFP, CEA and hCG	AFP, hCG, CEA	5	12
Pregnancy testing	Qualitative & quantitative hCG	2	12
Maternal serum screening	NTD (AFP) Second trimester Down's (AFP, hCG, UE3, inhibin) First trimester Down's (hCGβ, PAPP-A) First trimester Down's (hCGβ, PAPP-A) using Dried Blood Spots [Pilot] PLGF (hCGβ, PAPP-A) using Dried Blood Spots [Pilot]	3 3 3 5 3	12 12 12 12 3

10. Processing UK NEQAS samples in your laboratory

10.1 Receipt and analysis

UK NEQAS samples are intended to monitor laboratory performance on routine patient specimens. **They should be treated in exactly the same way as routine clinical samples.**

Please contact us immediately if you receive incorrect or damaged specimens, and replacements will be sent.

10.2 Return of results

Results must be returned within 3 weeks of the date of specimen issue if they are to be included in the monthly report. Results may be returned by post, fax, telephone or e-mail, or via the UK NEQAS web based results service at https://results.ukneqas.org.uk/. A password, available from UK NEQAS, is required for data entry via the website. Reporting *via* the internet is strongly encouraged. **Please take care to write results clearly, especially when faxing them.**

10.3 Failure to return results

If you make no response to a distribution by the due date your report will state “This laboratory has failed to return any results for this distribution”. Regular participation is important if adequate data are to be obtained, and is one of the criteria of good performance.

If you fail to return results for three consecutive distributions, you will be regarded as having poor performance and you will be contacted by senior scheme staff.

If you are unable to report results on a distribution, the report form should be returned with an explanation. Your results will be entered as “Null” and you will be sent a report in the usual way.

10.4 Late returns

We always accept and process late results provided there is a legitimate explanation (e.g. delayed arrival of specimens). If you return results after the due date they will be added to your cumulative record of performance and you will be sent a full report. Reports may be flagged as “Late” unless there are extenuating circumstances and at the discretion of the Scheme Director.

10.5 Errors and their correction

Causes of errors (which may or may not be classified as outliers) include

- Assaying the wrong samples.
- Assaying the right samples in the wrong order.
- Incorrectly transcribing laboratory results from computer systems or worksheets to results documents or the web entry system.
- Using incorrect units and/or conversion factors.
- Technical errors, e.g. incorrect reconstitution, incomplete mixing after thawing, faulty sampling/pipetting etc.

Such errors can be corrected but the error and the cause identified will be recorded separately and results marked as amended.

Amendments prior to reporting deadline Amended copies of results that have already been faxed or posted should be clearly marked as such with the change unambiguously highlighted.

Amendments after the reporting deadline Please contact us (telephone, fax or e-mail) to explain the problem. Results can usually be amended and an updated report produced.

Amendments after receipt of reports These should be reported in writing with an explanation of the reason for any amendment. Where investigation reveals the cause of the error, and repeat results are available, correction of the original results is permissible. However, the fact that you reported incorrect results will be recorded. Each incorrect result is counted as one error. Transcription errors in the Pregnancy Testing Scheme are generally not corrected because such errors are likely to reflect what happens in clinical practice.

10.6 UK NEQAS [Edinburgh] errors

If you suspect that we have made an error please let us know immediately.

We review all such errors carefully and it is important that we know about them so that we can audit and improve our service. Errors made by UK NEQAS [Edinburgh] will be corrected without penalty to the laboratory. Corrected reports will be accompanied by an apology.

10.7 Status of reports

The most recent versions of all reports are always those uploaded to the Results website. These will include results that have been received or amended after the first scheduled analysis so there may be minor differences in numerical details, e.g. the number of participants returning results. If it has been necessary for any reason to re-analyse and re-upload all reports for a given distribution (e.g. due to an error identified subsequent to the first upload) this will be clearly stated and the reason explained in the Comments section to the report.

11. Performance assessment

11.1 Target values

UK NEQAS attaches great importance to validation of target values, rather than simply accepting consensus means as the "correct" result.

Target values should be accurate and stable, but this is difficult to test for peptide hormones and tumour markers, where reference methods are generally not available. However some evidence for the validity of the consensus mean target values can be obtained by testing the recovery, linearity and stability of these targets at regular intervals. For most schemes in which quantitative results are reported, the all-laboratory trimmed mean (ALTM) is used as the target, but in several schemes grouped-method means are used as they are scientifically more appropriate (e.g. in the schemes for PAPP-A and UE3). Assigned values are selected as the best estimate of the true value.

Specialised schemes may have different targets. For example, the target for risk assessment in the Maternal Serum Screening schemes is the median of laboratory estimates of risk. Achieving consensus in the Pregnancy Testing scheme requires that at least 80% of participants using methods with the same claimed detection limit must agree.

11.2 Calculation of analytical performance scores (Schemes in which quantitative results are reported)

See page 24 for a worked example of the calculation of BIAS and VAR.

Laboratory performance is reported as **BIAS**, which is the mean percentage deviation from target, and **VAR** which measures the consistency of bias. BIAS and VAR are updated on a rolling basis across six distributions, i.e. the oldest data are removed from the laboratory record as new data are added. Note that some samples (e.g. those of low concentration or those containing added exogenous analyte) are routinely excluded from these calculation. A minimum of ten usable values is required to compute BIAS and VAR.

11.3 Calculation of analytical performance scores (Maternal serum screening: risk estimates)

See page 27 for a worked example of the calculation of risk scores.

Laboratory performance is reported as

1. **Running risk score (RRS)** Designed to be analogous to BIAS. RRS is the median of risk scores (RS) recorded during the time window (most recent six distributions). At least ten risk scores are needed to calculate the RRS, which should be close to zero.
2. **Non-parametric estimate of the SD of RRS (SDRRS)** Designed to be analogous to VAR. SDRRS is the non-parametric standard deviation (SD) of the RRS. Calculated as the median of the absolute differences between RS and RRS, the SDRRS should be close to zero.

11.4 Calculation of analytical performance scores (Pregnancy testing: qualitative hCG)

See page 27 for a worked example of the calculation of qualitative scores.

Results may be reported as “positive” (P), “negative” (N) or “equivocal” (E). The target for scoring purposes is the consensus of results reported by all users of the relevant method grouping. Each result is given a score according to its relationship to the consensus. Laboratory performance is then calculated as the sum of these performance scores over the last six distributions. A minimum of six usable results are required.

12. Performance criteria

12.1 Limits for acceptable performance

Limits for acceptable performance are approved by the National Quality Assurance Advisory Panel for Chemical Pathology (NQAAP) in consultation with the Specialist Advisory Group for Immunoassay.

The limits reflect clinical requirements, the state of the art for the analyte, and the need for regular quality assurance monitoring.

The criteria include acceptable limits for BIAS and VAR, and for return rate and are summarised in Appendix 2. BIAS and VAR criteria have not been established for all analytes and no performance criteria have been defined for the running risk scores (Maternal Serum Screening) or the quantitative scores (Pregnancy Testing).

The monthly reports include figures to show individual performance in relation to the relevant criteria. Laboratories should aim to maintain performance within these limits and are invited to contact us if problems appear to be developing, whether in analytical performance or in the ability to maintain regular returns.

12.2 Persistent poor performance and action taken

UK clinical laboratories are subject to NQAAP surveillance and should be aware of the conditions of participation (Appendix 1).

A laboratory is considered to be a persistent poor performer for a given analyte if

- Its cumulative performance is outside the prescribed limit for BIAS and/or VAR for three consecutive months,

or if

- It fails to return results for three consecutive months.

We will generally make informal contact with any participant falling into the above categories. If performance fails to improve, the Chairman of the appropriate NQAAP will be notified. Advice is then offered to the head of the laboratory in writing or, where appropriate and rarely, following a visit to the laboratory from a NQAAP Member or other appropriate expert.

12.3 Suspected collusion

Clearly participation in external quality assessment is beneficial when specimens are treated in the same way as patient specimens (e.g. assayed only once and without conferring with any other laboratory). All submitted results are inspected by UK NEQAS staff prior to analysis using dedicated checklists. Any suspicion of collusion (e.g. identical sets of results reported) will be investigated thoroughly and may include requesting copies of the relevant original analyser print-outs of results.

12.4 Disclosure of assigned values prior to data analysis

Details of specimen composition and/or expected results are not disclosed to participants until analysis of the results is completed and reports finalised. Rarely, and only in exceptional circumstances and at

the discretion of the Scheme Director, these details may be disclosed to individual participants in advance, e.g. where a performance issue that may adversely affect patient results has been identified and urgent independent confirmation of a potential problem is required.

13. Reports and their interpretation

All participants can view their reports on the UK NEQAS Results Website at https://results.ukneqas.org.uk/. A password is required and can be obtained from UK NEQAS [Edinburgh]. Printed copies of reports are also mailed to participants requesting these. Reports on the website are as obtained at the time of the initial analysis of the results submitted unless otherwise notified to participants, e.g. by e-mail. Reports rarely have to be reissued but if this is necessary it is clearly indicated in the box at the bottom of the first page of the reissued report. [Late and amended reports are marked as such in a box at the top right of the first page of the report.]

13.1 Quantitative schemes (BIAS and VAR scoring)

13.1.1 Overview

The report format is similar to that used in many other UK NEQAS schemes and contains the following sections:

1. **A summary**. This shows your performance for all analytes on the current distribution, and your current cumulative BIAS and VAR. This may be all you need to consult if performance is stable.
2. **Details of performance for each analyte.** This shows method performance on the current distribution, and tabulates all results for an individual participant for the most recent six distributions. Consult this section if you need to review your performance, or if you need information on method performance.
3. **Comments.** This section amplifies the data in the sections above, or may describe the results of surveys, e.g. interpretation of results. Summaries of recent literature are supplied in most schemes.

See pages 15 to 19 for examples of UK NEQAS monthly reports, with explanatory notes.

13.1.2 Interpretation of BIAS and VAR cumulative performance data

Calculation of BIAS and VAR by combining results from different pools at different concentrations over six distributions is designed to maximise use of the data, but introduces certain constraints in the interpretation of these performance statistics. These are illustrated in the examples below. Interpretation of BIAS and VAR is always assisted by examining the “Analysis of Bias” table which shows performance by pool and distribution (page 18) over a six month window. The figures may be interpreted as follows:

Low BIAS, low VAR

The assay is precise and is giving results close to the target value in the concentration range assessed. This represents desirable performance, assuming accuracy of the target value.

Low BIAS, high VAR

There is wide scatter of bias on individual specimens, although the mean ratio to the target value is near unity. There are several sources of high variability, including

1. Between- and within-assay imprecision
2. Dose-related differences in bias
3. Pool-related differences in bias

The “Analysis of Bias” table will help to identify which, if any, of the above is most relevant. As the VAR essentially provides an indication of the

confidence with which the mean BIAS can be estimated, it would be wrong under these circumstances to be too complacent about low BIAS.

High BIAS, low VAR

The assay is clearly biased relative to the target value, the ratio of individual results to ALTM (or GLTM) results being relatively constant over the concentration range assessed. Common causes of this include errors in standardisation (e.g. calibrator change, wrongly prepared or degraded calibrators), errors in conversion of results to the units used by UK NEQAS (e.g. wrong factor, wrong mathematics) and differences in assay specificity.

High BIAS, high VAR

There is a wide scatter of deviation from target on individual specimens, superimposed on a shift from unity in the mean ratio of results to the ALTM (or GLTM). The above comments on high VAR apply. The BIAS cannot be reliably estimated while the VAR remains high, and elimination of the sources of variability should be a first priority.

Note that if an assay is biased and steps are taken to correct this, VAR will remain high temporarily while the gradually improving BIAS passes through the six distribution window.

13.2 Risk estimates (maternal serum screening)

See pages 20 and 21 for examples of UK NEQAS risk estimate reports, with explanatory notes.

The report is similar in style to the "BIAS and VAR" report described above and contains the following sections:

1. Information on the specimens in the current distribution. A histogram shows the distribution of risk estimates returned by all participants using the relevant combination of analytes.
2. Summary data for the six most recent distributions. All the relevant risk estimates and their targets are shown in a table, and trends in cumulative risk scores are shown.

13.2.1 Interpretation of cumulative risk scores

The target for scoring risk estimates is simply the median of all estimates returned by participants using the relevant combination of analytes. This target is pragmatic and cannot be validated. With this proviso, participants should have running risk score (RRS) and standard deviations of running risk score (SDRRS) close to zero. The figures may be interpreted as follows:

High RRS, low SDRRS

Risk estimates are biased to the target values, but consistent.

Near-zero RRS, high SDRRS

On average, risk estimates are close to the targets, but their scatter is wide, suggesting some imprecision in the estimation of risk.

High RRS, high SDRRS

Risk estimates may be both imprecise and inaccurate.

13.3 Pregnancy Testing

See pages 22 and 23 for examples of Pregnancy Testing reports, with explanatory notes.

The reports are organised by analyte, with no summary page. Participants reporting qualitative results receive a personalised report which includes the following information:

Panel 1. Distribution number, date of return, and lab number.

Panel 2. Specimen and pool numbers for the current specimens together with a brief description of their content.

Panel 3. Pie charts showing for each specimen the % distribution of results [positive (P), negative (N) or equivocal (E)] and the consensus results. Individual laboratory results, and the score for this distribution, are also shown.

Panel 4. A single pie chart showing the percentage of usable specimens distributed (P, N and E) during the previous six months, followed by pie charts showing the laboratory's cumulative data for each type of specimen (P, N and E).

Panel 5. A graph showing the trends in cumulative interpretation score over the previous twelve months. [The cumulative score at each distribution is based on results for the previous six distributions.] There is also a table tabulating the laboratory's performance for each specimen.

Panel 6. A paragraph explaining the scoring system in use. [See page 28 for details.]

Participants reporting quantitative results receive a summary report similar to that in the serum hCG scheme. [These reports are for information only and results are not scored.]

A separate section tabulating all results received from users of all methods accompanies the personalised report.

13.3.1 Interpretation of cumulative interpretation scores

This score for qualitative results provides a measure of the level of agreement of individual results (positive, negative or equivocal) with the consensus result, averaged over six distributions. A score of zero shows complete agreement with the consensus. Positive scores suggest lack of agreement of the results with the consensus.

14. Previously issued specimens

Aliquots of previously issued specimens with target values can usually be provided to participants wishing to check existing assays or to evaluate new ones. An additional charge will normally not be made for such specimens. Specimens may also be available to manufacturers wishing to trouble-shoot existing assays or to evaluate new ones. A charge may be made for this service.

15. Customised reports

Special reports may be prepared to meet specific requirements, e.g.

Method reports, which can assist participating manufacturers in monitoring their products and participants evaluating methods or during tendering.

Laboratory subgroup reports for regional QA or Audit activities

16. Service development and scientific support

UK NEQAS [Edinburgh] is advised by the Specialist Advisory Group for Immunoassay and the Specialist Advisory Group for Maternal Serum Screening, which provide scientific advice. The Advisory Groups report to the UK NEQAS Steering Committee for Clinical Chemistry, which considers over-arching strategic issues. [For current membership of these groups please see Appendix 3.]

17. Comments and complaints

Comments about any aspect of the service, whether scientific or operational are welcome. In the event of complaints about day to day operational matters, please provide your laboratory number, scheme, distribution number and specimen number(s). Problems will be addressed as soon as possible.

Complaints can also be referred to any member of the Specialist Advisory Groups or Steering Committee (Appendix 3).

UK NEQAS [Edinburgh] is always pleased to receive suggestions from participants about ways in which the service provided could be improved.

18. Annual review

An *Annual Review* of the UK NEQAS results for the previous year, including analysis of long-term trends in participation and method performance, is prepared each year.

UK NEQAS reports and performance calculations - Illustrated examples

Terminology

ALTM	The All Laboratory Trimmed Mean, which is the geometric mean of the entire set of trimmed results for a specimen.
BIAS	The geometric mean of the trimmed deviations of your laboratory's results from their targets for all usable specimens for which you have returned results during the current six months.
CUMULATIVE INTERPRETATIVE SCORE (Pregnancy testing)	The sum of your scores over the last six distributions.
DEVIATION (dev'n)	The difference between your result and the target result, expressed as a percentage of the target.
DISTRIBUTION	A group of specimens in a particular scheme that are sent together to each participating laboratory.
GCV	The geometric coefficient of variation of the results in a set or sub-set of results.
GLTM	The geometric mean of a sub-set of the trimmed results for a specimen. The sub-set may be a group of inter-related methods.
LSD	The linear estimate of the standard deviation of the log transformed, trimmed results.
MAXIMUM NUMBER OF RESULTS	Number of usable specimens issued in the current six months.
MLTM	The geometric mean of the trimmed results for a specimen observed by users of one method.
NUMBER OF RESULTS	Number of usable specimens for which your laboratory has returned numerical results.
OUTLIER (BETWEEN-LABORATORY, WITHIN-SPECIMEN)	A result that is more than three LSD's from the appropriate target. These outliers demonstrate an inability to agree with your peers.
OUTLIER (WITHIN-LABORATORY, BETWEEN-SPECIMEN)	A result that has a deviation that is more than three SD's from your cumulative BIAS. These results are rather less significant, as they depend on your VAR. A relatively small deviation would be flagged if you have a low VAR, but would not be flagged if your VAR were high.
POOL	A bulk preparation of serum usually prepared from several individual donations.

RS (Risk score)	A score representing the deviation of your risk estimate from consensus.
RRS	The median of your risk scores (RS**)** over the last six distributions.
SAMPLE	An alternative term for specimen.
SCORE (Pregnancy testing)	A score representing the deviation of your result (positive, negative or equivocal) from consensus.
SDRRS	The standard deviation of your RRS. It is an estimate of spread of risk estimates.
SPECIMEN	An aliquot of a given pool. The same pool may be issued on more than one occasion with different specimen numbers.
TRANSFORMATION	The process of converting results to their natural logarithms in order to correct for skew of the raw distribution prior to statistical analysis.
TRIMMING	The effect of aberrant results that may be present is minimised by trimming the data prior to statistical analysis. The chosen method is that of Healy, which involves trimming of the lowest and highest 5% of results, (see Page 18). Note that trimmed results are not necessarily outliers.
USABLE SPECIMEN	A specimen that has no unusual or unacceptable features will be deemed to be usable for the calculation of cumulative BIAS and VAR. Unusable specimens include those with analyte concentrations near the detection limits of the assays and those with added interfering substances.
VAR	The variability or GCV of the BIAS, or scatter of the deviations of your results from target for all usable specimens in the six distributions to date. VAR reflects imprecision, but is affected by dose or specimen related bias.

Distribution number

Last date for return of results

Lab number

UK NEQAS [Edinburgh]

UK NEQAS for Peptide Hormones

Distribution : **439** Date : 09-Aug-2016

Laboratory :

Distribution Summary

FSH (U/L IRP 78/549)	**G211** G581	**G212** G582	**G213** G583	**G214** G584	**G215** G585
Your result	1.0	3.7	7.7	2.4	19.6
Target (ALTM)	1.1	3.8	8.5	2.6	19.6
Your specimens bias(%)	-9.0	-3.0	-9.0	-6.3	-0.1

Your method is Abbott Architect
Your BIAS (%) is -7.1
Your VAR (%) is 6.1

LH (U/L IS 80/552)	**G211** (G581)	**G212** G582	**G213** G583	**G214** G584	**G215** G585
Your result	(0.3)	5.5	10.3	1.9	6.9
Target (ALTM)	(0.3)	7.1	14.9	2.6	9.5
Your specimens bias(%)	(-13.8)	-22.0	-30.8	-27.4	-27.0

Your method is Abbott Architect
Your BIAS (%) is -25.0
Your VAR (%) is 6.9

Prolactin (mU/L IS 84/500)	**G211** G581	**G212** G582	**G213** G583	**G214** G584	**G215** G585
Your result	242	298	241	174	132
Target (ALTM)	239	298	248	176	162
Your specimens bias(%)	+1.1	-0.1	-2.7	-1.2	-18.5

Your method is Abbott Architect
Your BIAS (%) is -2.1
Your VAR (%) is 7.4

AMH (pmol/L)	**G211** G581	**G212** G582	**G213** G583	**G214** G584	**G215** G585
Your result	19.4	34.0	13.7	53.2	16.9
Target (ALTM)	19.1	32.2	13.5	49.4	16.9
Your specimens bias(%)	+1.6	+5.7	+1.2	+7.8	+0.1

Your method is Beckman Access Access 1 & 2
Your BIAS (%) is -0.5
Your VAR (%) is 5.5

Growth Hormone (ug/L IS 98/574)	**H211** W060	**H212** (W061)	**H213** (W062)	**H214** (W063)
Your result	1.3	(18.1)	(3.2)	(12.8)
Target (ALTM)	1.12	(17.50)	(2.92)	(11.76)
Your specimens bias(%)	+16.1	(+3.4)	(+9.6)	(+8.9)

Your method is S Im2000 family Immulite 2000, XPi
Your BIAS (%) is +10.4
Your VAR (%) is 6.4

Results for the current distribution (for all analytes for which you are registered) showing:

- Pool and specimen numbers
- Concentration units
- Your results
- Target results
- Your specimen bias (% deviation from the target)

Cumulative statistics from the last six distributions showing:

- Your method
- Your cumulative bias from the target (BIAS)
- The cumulative variability (scatter) of your bias (VAR)

Pools that have been excluded for the calculations of the cumulative statistics, and other general information.

POOLS EXCLUDED FROM THE CUMULATIVE STATISTICS:

Pool G581 for LH and Pools W061, W062 and W063 for growth hormone have been excluded from all calculations of the cumulative statistics.

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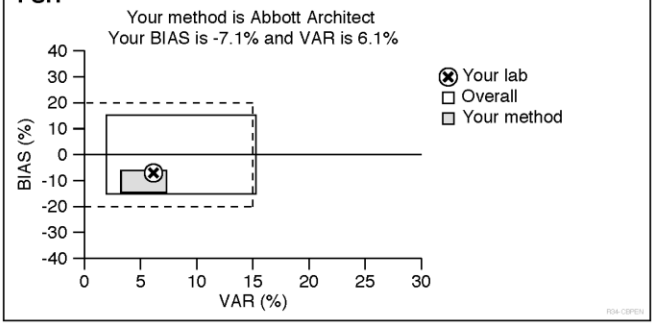
These BIAS and VAR plots are intended to give you a graphical representation of your performance relative to that of all other participants.

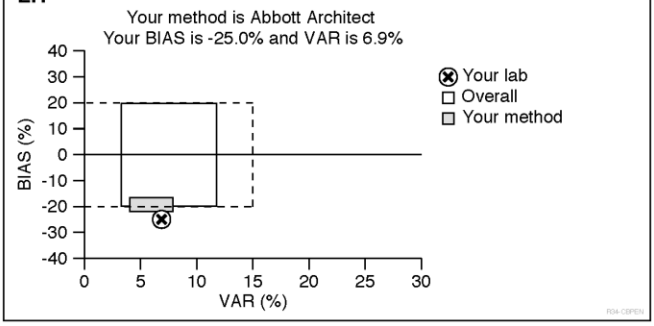
Your own, current BIAS and VAR are marked with an "X". Data for other users of your method are also plotted individually if less than ten laboratories use it. Otherwise, your method performance is shown by a shaded box bounded by the 5th and 95th centiles of BIAS and VAR. Similarly, an open box with the same bounds is plotted for All Participants.

The dotted lines on the graphs for analytes expressed in concentration units and in MoMs represent the limits of acceptable performance defined by the National Quality Assurance Advisory Panel for Chemical Pathology.

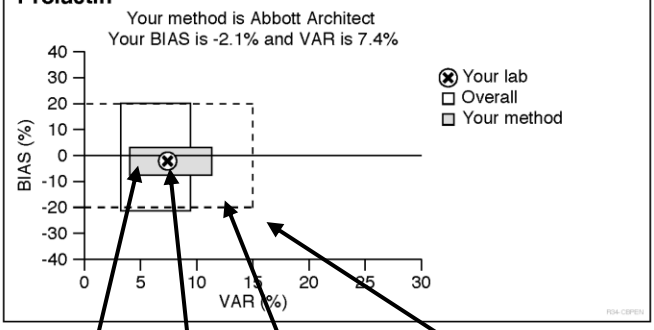
FSH



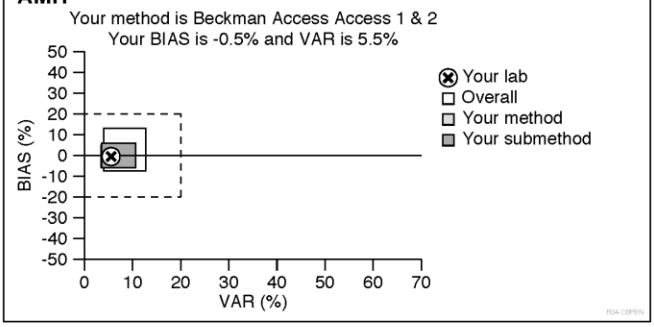
LH



Prolactin



AMH



Your lab

All methods

Limits of acceptable BIAS and VAR as defined by the NQAAP.

Your method

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Pool descriptions (including "special" samples - check)

Your cumulative performance over the last six distributions.

UK NEQAS [Edinburgh]

UK NEQAS for Peptide Hormones

Laboratory :

Distribution : **439** Date : 09-Aug-2016

Analyte : FSH (U/L IRP 78/549)

Spec.	Pool	Pool description
G211	G581	Base pool of normal human serum.
G212	G582	Base pool of normal human serum.
G213	G583	Base pool of normal human serum.
G214	G584	Base pool of normal human serum.
G215	G585	Base pool of normal human serum.

□ All methods
▒ Abbott Architect

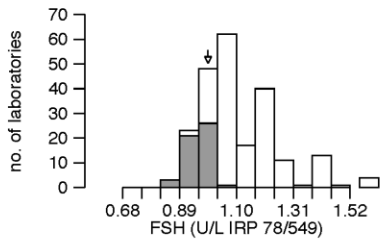
Your BIAS (%) is -7.1

Your VAR (%) is 6.1

Your method is : Abbott Architect

Specimen : G211

	n	Mean	GCV	Outl.
All methods	223	1.1	13.2	0
Abbott Architect	51	1.0	6.1	0
Beckman Access	24	1.2	9.1	0
Dxl	18	1.2	10.4	0
Roche Elecsys	93	1.1	5.9	0
E170, e601, e602	88	1.1	5.9	0
Siemens A Centaur	34	1.3	16.3	0
Siemens I2000fam	12	1.0	4.5	0
Immulite 2000, XPi	12	1.0	4.5	0



Your result 1.0

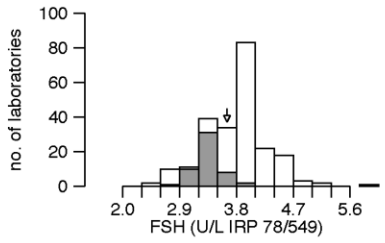
Your target 1.1

Your deviation (%) -9.0

Standard Uncertainty 0.01

Specimen : G212

	n	Mean	GCV	Outl.
All methods	225	3.8	12.8	0
Abbott Architect	52	3.4	5.8	0
Beckman Access	24	4.3	8.2	0
Dxl	18	4.3	9.0	0
Roche Elecsys	94	3.9	3.1	0
E170, e601, e602	89	3.9	3.1	0
Siemens A Centaur	34	4.3	5.9	0
Siemens I2000fam	12	2.8	5.8	0
Immulite 2000, XPi	12	2.8	5.8	0



Your result 3.7

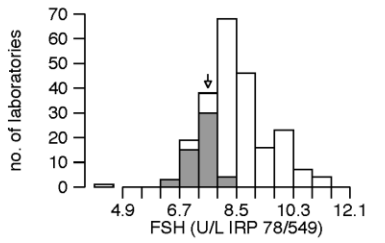
Your target 3.8

Your deviation (%) -3.0

Standard Uncertainty 0.04

Specimen : G213

	n	Mean	GCV	Outl.
All methods	225	8.5	12.4	0
Abbott Architect	52	7.4	4.9	0
Beckman Access	24	9.3	7.5	0
Dxl	18	9.3	8.1	0
Roche Elecsys	94	8.4	4.0	0
E170, e601, e602	89	8.4	4.0	0
Siemens A Centaur	34	10.0	5.6	0
Siemens I2000fam	12	8.7	2.5	0
Immulite 2000, XPi	12	8.7	2.5	0



Your result 7.7

Your target 8.5

Your deviation (%) -9.0

Standard Uncertainty 0.09

Panels for each specimen showing data for all methods, major methods and sub-methods. Data shown are:

- Number of labs that have returned results
- Mean of results
- Spread of results (GCV)
- No. of outliers (>3 SD from target)

Histogram showing distribution of:

- All results (no shading)
- Your method (dark shading)
- Your sub-method (if applicable, light shading)
- Your own result (arrow)

Your results:

- Your result
- Target value
- Your % deviation from target

Further information on pools

Pools: All pools have been included in all calculations of the cumulative statistics.

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Each column shows your result, the target value and % bias for each specimen in a single distribution.

NEQAS for Peptide Hormones | Laboratory :

tribution : **439** Date : 09-Aug-2016 | Page 4 of 17

UK NEQAS [Edinburgh] | Analyte : FSH (U/L IRP 78/549)

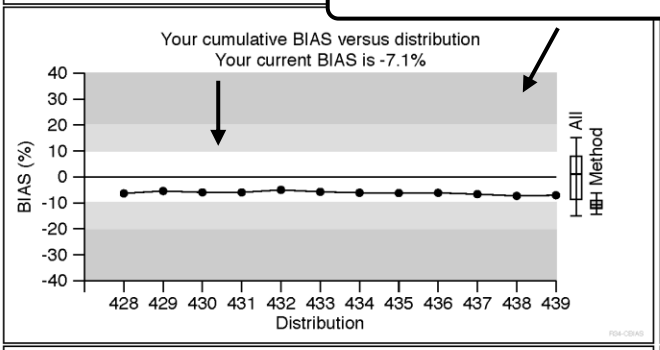
Pool (exclusion) [Type]	Distribution 434 22-Mar-2016 result	target	%bias	Distribution 435 19-Apr-2016 result	target	%bias	Distribution 436 17-May-2016 result	target	%bias	Distribution 437 14-Jun-2016 result	target	%bias	Distribution 438 12-Jul-2016 result	target	%bias	Distribution 439 09-Aug-2016 result	target	%bias
G581 [B]																1.0	**1.1**	-9.0
G570 [B]										1.3	**1.5**	-13.2						
G568 [B]							1.4	**1.7**	-17.4									
G564 [B]				2.2	**2.5**	-13.4												
G584 [B]																2.4	**2.6**	-6.3
G558 [B]	2.7	**2.9**	-8.4															
G560 [B]				2.8	**2.9**	-3.4												
G579 [X]													3.2	**3.8**	-15.3			
G582 [B]																3.7	**3.8**	-3.0
G580 [X]													3.2	**3.8**	-15.4			
G576 [B]													3.4	**3.8**	-11.3			
G573 [B]										3.8	**4.1**	-8.2						
G565 [B]							3.9	**4.4**	-12.3									
G561 [B]				4.3	**4.7**	-8.0												
G553 [B]	4.7	**5.1**	-8.7															
G571 [B]										5.1	**5.2**	-1.1						
G574 [B]										5.1	**5.3**	-3.7						
G572 [B]										6.6	**7.0**	-5.4						
G567 [B]							7.3	**7.4**	-1.0									
G559 [B]	7.7	**7.9**	-3.1															
G566 [B]							7.6	**8.1**	-6.2									
G583 [B]																7.7	**8.5**	-9.0
G562 [B]				8.7	**8.9**	-1.8												
G557 [B]																		
(G578) [X]													(9.9)	**(11.4)**	(-13.0)			
G563 [B]																		
G585 [B]																19.6	**19.6**	-0.1
G569 [B]							19.2	**19.9**	-3.5									
(G577) [X]													(29.4)	**(33.6)**	(-12.4)			
G555 [B]																		
Method Mean bias						6.8	Abbott Architect		-8.1	Abbott Architect		-6.3	Abbott Architect		-14.0	Abbott Architect		-5.5
BIAS (%)	-6.1			-6.2			-6.1			-6.6			-7.3			-7.1		
VAR (%)	4.2			3.9			4.5			4.7			6.3			6.1		

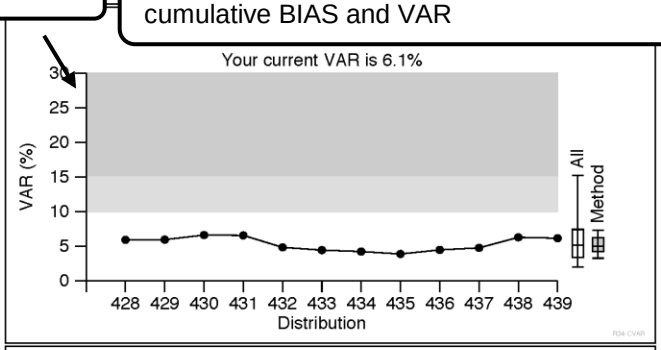
Pools listed in order of concentration. ( ) indicates pool excluded from statistics. [ ] indicates type of pool.

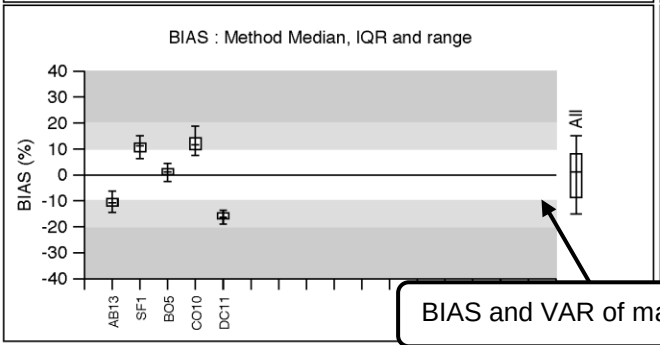
B Base pool, no additions made.
X Exogenous hormone added (IRP IS, etc.)

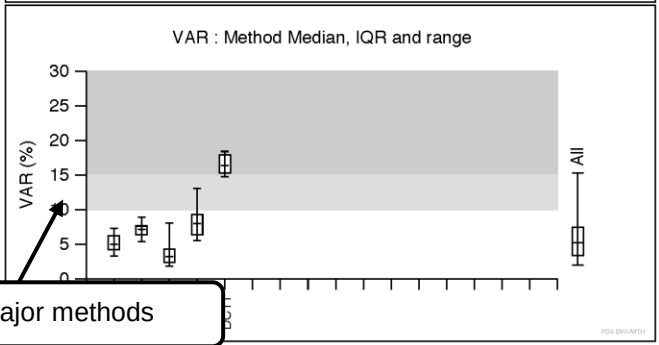
Trends in your BIAS and VAR

Your method, monthly mean % deviation, cumulative BIAS and VAR









BIAS and VAR of major methods

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		G211			G212			G213			G214			G215		
	n	Mean	GCV	Outl.	Mean	GCV	Outl.	Mean	GCV	Outl.	Mean	GCV	Outl.	Mean	GCV	Outl.
All methods	225	1.1	13.2	0	3.8	12.8	0	8.5	12.4	0	2.6	13.1	0	19.6	8.1	0
Abbott Architect	52	1.0	6.1	0	3.4	5.8	0	7.4	4.9	0	2.3	4.9	0	18.5	5.0	0
Beckman Access	24	1.2	9.1	0	4.3	8.2	0	9.3	7.5	0	2.9	8.7	0	21.9	4.5	0
1 & 2	6	1.2	1.2	0	4.2	6.8	0	9.3	7.8	0	2.8	6.7	0	21.9	5.7	0
DxI	18	1.2	10.4	0	4.3	9.0	0	9.3	8.1	0						
Roche Elecsys	94	1.1	5.9	0	3.9	3.1	0	8.4	4.0	0						
E170, e601, e602	89	1.1	5.9	0	3.9	3.1	0	8.4	4.0	0						
Siemens A Centaur	34	1.3	16.3	0	4.3	5.9	0	10.0	5.6	0						
Siemens I2000fam	12	1.0	4.5	0	2.8	5.8	0	8.7	2.5	0						
Immulite 2000, XPi	12	1.0	4.5	0	2.8	5.8	0	8.7	2.5	0						

Mean data for the current distribution for all methods with five or more users.

			BIAS			VAR		
		n	Median	Interquartile range		Median	Interquartile range	
All methods		226	+1.1	-8.7	+8.1	5.2	3.4	7.4
Abbott Architect	AB13	48	-10.7	-12.0	-9.2	5.0	4.2	6.2
Beckman Access	SF1	24	+11.1	+8.9	+12.3	7.1	6.4	7.6
1 & 2		6	+11.2	+9.5	+11.8	7.5	6.5	7.7
DxI		18	+11.1	+8.5	+12.4	7.0	6.4	7.5
Fortress Diagnostics ELISA	FO1	1	+4.0	+4.0	+4.0	26.9	26.9	26.9
OCD (J&J) VITROS	AM12	4	-14.7	-16.6	-13.2	9.9	8.4	11.7
P E DELFIA	PH2	2	-14.8	-15.3	-14.3	4.3	4.0	4.5
AutoDELFIA		1	-13.9	-13.9	-13.9	3.8	3.8	3.8
Manual DELFIA		1	-15.8	-15.8	-15.8	4.8	4.8	4.8
Roche Elecsys	BO5	94	+1.1	+0.1	+2.3	3.2	2.3	4.2
1010, 2010, e411		5	+2.8	+0.9	+2.8	4.5	2.8	6.4
E170, e601, e602		88	+1.0	0.0	+2.2	3.2	2	
Siemens A Centaur	CO10	37	+11.6	+9.8	+14.2	7.9	6	
Siemens I2000fam	DC11	12	-16.2	-16.8	-14.6	16.4	15	
Immulite 2000, XPi		12	-16.2	-16.8	-14.6	16.4	15	
Tosoh AIA	TO1	4	+29.8	+27.8	+32.1	5.0	3.7	6.7

Cumulative BIAS and VAR figures for all methods.

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Spec.	Pool	Pool description
D895	R486	Base pool of first trimester pregnancy sera.
D896	R487	Base pool of second trimester pregnancy sera.
D897	R488	220 mL of Pool R486 plus 30 mL of Pool R487.

AFP+fb-hCG+UE3+IA

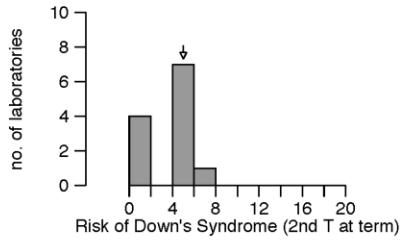
Your cumulative scores.

Running risk score (RRS) +1.0

NP-SD of RRS (SDRRS) +1.0

Specimen : D895

	n	Median	NPCV
AFP+fb-hCG	11	7	29
AFP+fb-hCG+UE3	15	5	0
AFP+fb-hCG+UE3+IA	12	5	0
AFP+t-hCG	10	10	32
AFP+t-hCG+UE3	24	5	60
AFP+t-hCG+UE3+IA	12	5	0



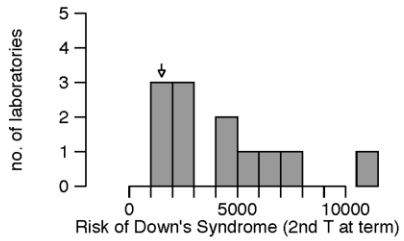
Your risk estimate 5

Your target risk 5

Your risk score +2.0

Specimen : D896

	n	Median	NPCV
AFP+fb-hCG	11	751	83
AFP+fb-hCG+UE3	15	1409	48
AFP+fb-hCG+UE3+IA	12	3522	52
AFP+t-hCG	10	1232	10
AFP+t-hCG+UE3	29	1828	26
AFP+t-hCG+UE3+IA	16	4138	30



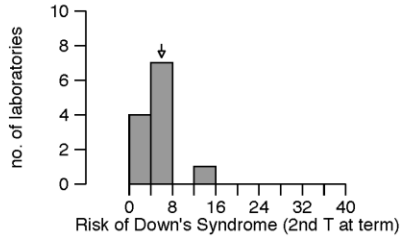
Your risk estimate 1719

Your target risk 3522

Your risk score -2.0

Specimen : D897

	n	Median	NPCV
AFP+fb-hCG	11	13	46
AFP+fb-hCG+UE3	15	5	0
AFP+fb-hCG+UE3+IA	12	5	20
AFP+t-hCG	10	18	35
AFP+t-hCG+UE3	24	6	64
AFP+t-hCG+UE3+IA	12	5	0



Your risk estimate 5

Your target risk 5

Your risk score +1.0

Summary data showing median risk and spread [i.e. non-parametric estimate of the coefficient of variation (NPCV)] for all sets of analytes.

Histograms showing all risk estimates returned by users of the same set of analytes as those used in your laboratory.

Summary data for each specimen, showing your risk, the target risk and your risk score (i.e. your deviation from target).

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Each column shows your risk estimates, targets and risk scores for specimens in a single distribution

UK NEQAS [Edinburgh]

EQAS for MSS - 2nd Trimester | Laboratory :

Distribution : **299** Date : 26-Jul-2016 | Page 35 of 41

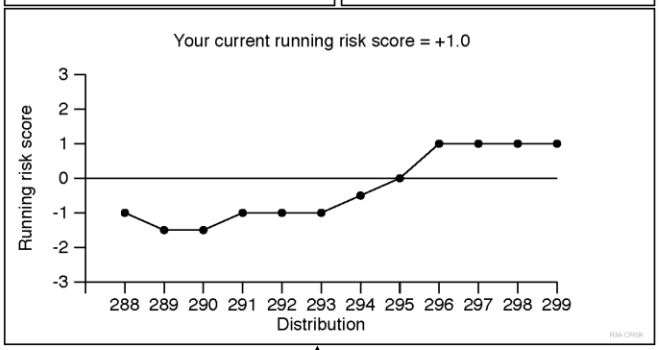
Analyte : Risk of Down's Syndrome (2nd T at term)

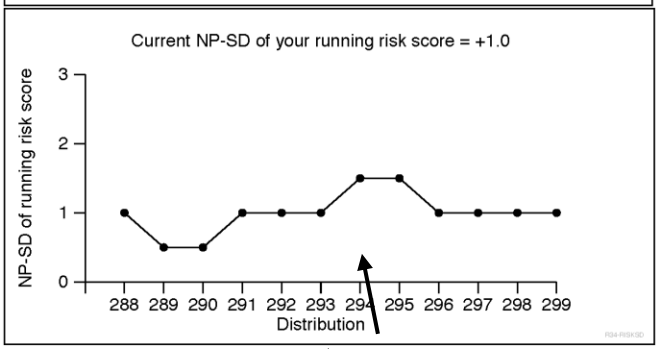
Pool (exclusion) [Type]	Distribution 294 08-Mar-2016			Distribution 295 05-Apr-2016			Distribution 296 03-May-2016			Distribution 297 31-May-2016			Distribution 298 28-Jun-2016			Distribution 299 26-Jul-2016		
	risk	**target**	score	risk	**target**	score	risk	**target**	score	risk	**target**	score	risk	**target**	score	risk	**target**	score
R481 [B]	5	**5**	+1.0															
R488 [B]							10	**5**	+2.0							5	**5**	+1.0
R490 [B]										6	**5**	+1.0	5	**5**	0.0			
R486 [B]				5	**5**	+2.0	5	**5**	+2.0							5	**5**	+2.0
R485 [B]	9	**10**	0.0															
R489 [B]				79	**36**	+2.0	55	**35**	+2.0									
R484 [B]	44	**47**	0.0															
R493 [B]										142	**91**	+2.0						
R492 [B]										243	**185**	+1.0	275	**170**	+1.0			
R491 [B]													1000	**1850**	-2.0			
R487 [B]				708	**4648**	-2.0										1719	**3522**	-2.0
Method	AFP+fb-hCG+UE3+IA			AFP+fb-hCG+UE3+IA			AFP+fb-hCG+UE3+IA			AFP+fb-hCG+UE3+IA			AFP+fb-hCG+UE3+IA			AFP+fb-hCG+UE3+IA		
Med.score			0.0			2.0			2.0			1.0			0.0			1.0
RRS	-0.5			0.0			+1.0			+1.0			+1.0			+1.0		
SDRRS	1.5			1.5			1.0			1.0			1.0			1.0		

Pools listed in order of median risk

Enables assessment of stability of targets and risks reported for the same pool if issued more than once.

B Base pool, no additions.





Trends in your funning risk score (RRS).

Trends in the non-parametric standard deviation (NP-SD) of your RRS (SDRRS)

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UK NEQAS [Edinburgh]

UK NEQAS for Pregnancy Testing

Laboratory :

Distribution : **220** Date : 26-Jul-2016

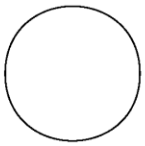
Analyte : Urinary hCG (Qualitative)

Spec.	Pool	Pool description / Treatments / Additions
X459	Q493	Urine from a single non-pregnant donor.
X460	Q494	Pregnancy urine from a single donor.

The pie charts in the boxes below and at left depict schematically the proportion of participants in your method group reporting negative (N), equivocal (E) or positive (P) qualitative results for Specimens X459 and X460.

Description of specimens and pools

Specimen : X459



Your score 0

Alere hCG

N = Negative
E = Equivocal
P = Positive

Specimen : X460

Your score 0

Alere hCG

N = Negative
E = Equivocal
P = Positive

Your result

Summary of responses for the specimens in the current distribution

Consensus

Your score

Your method

Specimens distributed in each category

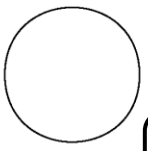
Methods are grouped according to their detection limits:

Quoted detection <50 U/L - ACCUSAY hCG One-Step Pregnancy Test,AI DE Diagnostics One-Step hCG Strip, Alere hCG Combo,Alere EASY hCG,Alere hCG,Alere SureStep hCG Combo,Alere SureStep hCG,Alere Testpack hCG Plus,Alere Testpack hCG Urine,Alere Testpack Plus hCG Combo,Axis-Shield One-Step Cassette,BioMerieux BioNexia,BioSign hCG,BioSign hCG DXpress Reader,Clearblue Pregnancy Test,Concateno FirstStep Dip and Read,Congene hCG Pregnancy Test Midstream,Homehealth Cassette,Homehealth Midstream,Homehealth Strip 10 U/L,Homehealth Strip 25U/L,Immunostics Immuno/Detector Combi,Innovacon SureStep One-Step Test,Invitech One-Step hCG Test Strip 25 U/L,Invitech One-Step hCG Test Strip 10U/L,Invitech One-Step hCG Test 10 U/L,NADAL hCG Pregnancy Test Strip 10U/L,Pasante MEDICheck Dip and Read,Quadratech Check 4 Strip,Quidel QuickVue One-Step,Quidel QuickVue Plus,Randox Rapid Pregnancy Test,Rapid Response One Step hCG 20 U/L,SAS Serum/Urine hCG Test,Siemens Clinitek STATUS,Stanbio QuPID Plus,Ultimed hCG Cassette,VEDA.LAB Rapid hCG One-Step,ZER Hitech Check-Mate One-Step

Quoted detection >/=50 and <200 U/L - Beckman Access

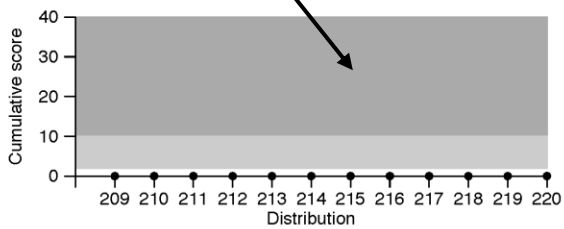
Your interpretation for each category

Negative



Positive

Trends in your cumulative interpretation score.



Dist	Spec	Score	Dist	Spec	Score	Dist	Spec	Score
209	X437	0	213	X445	0	217	X453	0
209	X438	0	213	X446	0	217	X454	0
210	X439	0	214	X447	Excluded	218	X455	Excluded
210	X440	0	214	X448	0	218	X456	0
211	X441	0	215	X449	0	219	X457	0
211	X442	Excluded	215	X450	0	219	X458	0
212	X443	0	216	X451	0	220	X459	0
212	X444	0	216	X452	0	220	X460	0

Your scores for each specimen in the time window

Cumulative Interpretive Scores

The acceptable performance limit set by the National Quality Assurance Advisory Panel for Chemical Pa
interpretive scores have therefore been divided into 3 categories and are represented on the graph abov

Desirable category (white area): Interpretive score of 0 **Acceptable category (pale grey area):** Interp
Unacceptable category (dark grey area): Interpretive score of >10

Summary of Scores: The right hand table above shows your score for each specimen over the 12 most recent distributions.

Owned and operated by NHS Lothian, UK NEQAS [Edinburgh] is located in the Dept of Laboratory Medicine, Royal Infirmary, Edinburgh EH16 4SA, UK.
These external quality assessment services are accredited by UKAS [Ref 8505].
Scheme website: edqas.org. Results website: https://results.ukneqas.org.uk

Published at 22:02 on Monday 29 August 2016

UK NEQAS [Edinburgh]

UK NEQAS for Pregnancy Testing

Distribution : **220** Date : 26-Jul-2016

Analyte : Urinary hCG (Quantitative) (U/L IS 75/589)

Laboratory :

Page 2 of 2

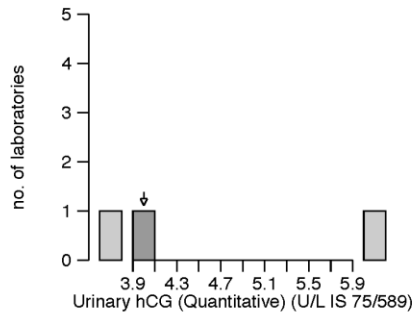
Spec.	Pool	Pool description
X459	Q493	Urine from a single non-pregnant donor.
X460	Q494	Pregnancy urine from a single donor.

□ All methods
▒ Total hCG methods
▓ I/H Dab RIA L/P

Your method is I/H Dab RIA L/P

Specimen : X459

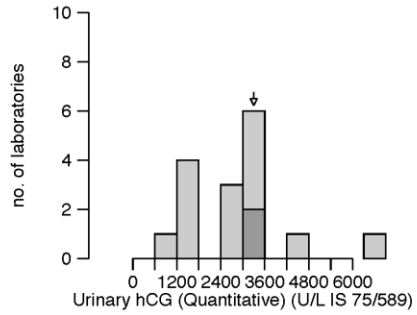
	n	Mean	GCV
All methods			



Your result	4
Your target ()	
Your deviation %	
Standard Uncertainty	

Specimen : X460

	n	Mean	GCV
All methods	16	2616	47.1
Total hCG methods	16	2616	47.1
Roche ElecSYS (Total)	7	3013	5.3



Your result	3086
Your target (GLTM)	2616
Your deviation %	+18.0
Standard Uncertainty	323.80

Summary data showing overall, method group and method means.

Histograms showing all results. Your result indicated by the arrow.

Your summary data for each specimen, showing your result, the target result and your deviation from target.

The histograms showing quantitative results are similar to those in the serum hCG scheme. Results for individual qualitative and quantitative methods are listed in the tables on the accompanying comments sheet.

Owned and operated by NHS Lothian, UK NEQAS [Edinburgh] is located in the Dept of Laboratory Medicine, Royal Infirmary, Edinburgh EH16 4SA, UK. These external quality assessment services are accredited by UKAS [Ref 8505]. Scheme website: edqas.org. Results website: https://results.ukneqas.org.uk

Published at 22:02 on Monday 29 August 2016

Calculation of BIAS and VAR: Cumulative performance statistics

Specimen and laboratory performance statistics are calculated after logarithmic transformation of results, using the trimming method of Healy MJR (*Clin Chem* 1979; **25**: 675-677). Logarithmic transformation allows for skewness in the data and appropriate computation of errors while trimming improves the reliability of the mean and measure of scatter.

1. SPECIMEN STATISTICS

1.1 All laboratory trimmed mean (ALTM) and its geometric coefficient of variation (GCV)

For each specimen non-numeric results, including those reported as "less than" or "greater than" are discarded. All remaining individual results are ranked and transformed into their natural logarithms. The lowest and highest 5% of results (rounded up to the nearest whole number) are trimmed (Healy, 1979). The excluded results play no part in the calculation of the estimate of the mean of the results (ALTM) or the scatter of values (GCV), but **are not necessarily outliers** and are therefore retrieved for the later identification of between-laboratory, within-specimen outliers and calculations of individual laboratory BIAS and VAR (see below).

1.2 Grouped laboratory trimmed mean (GLTM) and its GCV

Calculations exactly analogous to those described above can be performed on results from groups of similar methods, such as assays of hCG classified according to recognition of the free β-subunit of hCG. The estimate of the mean is referred to as the GLTM, and its associated estimate of scatter is the GCV.

1.3 Method laboratory trimmed mean (MLTM) and its GCV

Calculations exactly analogous to those described above can be performed on results from a single method. The estimate of the mean is referred to as the MLTM, and its associated estimate of scatter is the GCV.

2. LABORATORY PERFORMANCE STATISTICS

2.1 Cumulative BIAS and its variability (VAR)

Cumulative bias (BIAS) and the variability of the bias (VAR) are calculated for each laboratory from all results returned by that laboratory on all usable specimens during the most recent six distributions (usually six months but 12 months for Peptide II).

Non-numeric results are discarded, as above, and the remaining results are transformed by taking natural logarithms. Deviations are calculated by subtracting the natural logarithm of the chosen target for the analyte in question (ALTM or GLTM) from these logarithmic values. (This is equivalent to division of untransformed values). The values are ranked and trimmed as above. The mean and LSD are calculated and within-laboratory, between-specimen outliers identified. The BIAS is then the antilog of this mean expressed as a percentage difference from 100 and the VAR is the GCV of the deviations.

3. WORKED EXAMPLE

The following gives a worked example from the prolactin NEQAS (specimen statistics) and the growth hormone NEQAS (laboratory statistics) and should be read in conjunction with Healy, 1979.

3.1 Specimen Statistics

3.1.1 Rank data, take natural logs, trim highest and lowest 5% and assign weightings. i = Rank of trimmed data, k = number of results after trimming

Lab	Raw result (mU/L)	Natural log (x)	Rank (i)	Weighting (2i-k-1)
12	260	5.5607		Trimmed
175	271	5.6021		Trimmed
1823	275	5.6167	1	24
14	278	5.6276	2	-22
272	280	5.6348	3	-20
408	280	5.6348	4	-18
39	280	5.6348	5	-16
38	280	5.6348	6	-14
17	281	5.6384	7	-12
1614	282	5.6419	8	-10
2	286	5.656	9	-8
80	288	5.663	10	-6
1	290	5.6699	11	-4
412	290	5.6699	12	-2
96	290	5.6699	13	0
86	290	5.6699	14	2
124	298	5.6971	15	4
701	298	5.6971	16	6
933	300	5.7038	17	8
48	300	5.7038	18	10
49	300	5.7038	19	12
627	303	5.7137	20	14
83	305	5.7203	21	16
1001	310	5.7366	22	18
11	310	5.7366	23	20
206	310	5.7366	24	22
216	320	5.7683	25	24
606	325	5.7838		Trimmed
74	340	5.8289		Trimmed

3.1.2 Choice of number of results to be trimmed

The number of results to be trimmed is that which would remove 10% of the sample (the lowest 5% and the highest 5%), rounded up to the next even number.

In this case, the number of raw results, n = 29, so the number trimmed is 10% of 29 = 2.9 which is rounded up to 4. Therefore, the lowest 2 results and the highest 2 results are removed. Number of results left after trimming, k = 25.

3.1.3 Calculate the ALTM

$$\text{Mean trimmed, transformed results, } \bar{x} = \frac{\sum_{i=1}^{k} (x_i)}{k} = 5.679$$

$$\text{ALTM} = e^{\bar{x}} = 292.7 \text{ mU/ L}$$

Where x_i = natural logarithm of i'th untrimmed result.
k = number of results remaining after trimming.

3.1.4 Calculate proportion untrimmed

Total number of results, n = 29
Number of results after trimming, k = 25

$$\text{Proportion untrimmed, } p = \frac{k}{n} = 0.8621$$

3.1.5 Obtain unbiasing factor

This is obtained from Healy, p 676

$$b_p = 2.359$$

3.1.6 Calculate linear estimate of the standard deviation, LSD

$$\text{LSD} = \frac{b_p \times \sum_{i=1}^{k} (2i - k - 1) \times x_i}{k\,(k - 0.5)}$$

In this example, k (k - 0.5) = 25 × 24.5 = 612.5

(2i - k - 1) = Weighting factor for each natural log value

Sum of products, ln(result) × weighting factor

$$= \sum_{i=1}^{k} (x_i \times \text{weight}_i) = 14.4752$$

$$\text{LSD} = \frac{2.359 \times 14.475}{612.5} = 0.05575$$

This figure is an estimate of the standard deviation of the natural log values which, in practice, is close to the figure for the proportional coefficient of variation.

Note that the LSD refers only to the log values. The antilog of the LSD is not an appropriate measure of the scatter of the raw data. To estimate the scatter we calculate the GCV (Kirkwood, TBC 1979. *Biometrics*;**35**:908-909) which is a multiplicative factor (see 3.1.7 below).

3.1.7 Calculate the geometric coefficient of variation

$$\text{GCV} = (e^{\text{LSD}} - 1) \times 100$$

$$e^{\text{LSD}} = 1.0573$$

$$\text{GCV} = 5.7\%$$

3.1.8 Identification of between-laboratory, within-sample outliers

An outlier is defined as a value outside the 99% confidence interval of the mean (of the logged results), which is approximately ± three (linear) standard deviations.

$$\text{From } (\bar{x} - (3 \times \text{LSD})) = 5.679 - 0.167 = 5.512$$

$$\text{to } (\bar{x} + (3 \times \text{LSD})) = 5.679 + 0.167 = 5.846$$

So, from section 3.1.1, we see that there are no between-laboratory, within-sample outliers. Note that trimmed results and outliers are not the same; trimmed results only become outliers if they are outside the ±3 LSD range from the mean.

3.2 Laboratory Statistics

The process is analogous to that described above, except that the starting data are an individual laboratory's results on all usable specimens obtained during the six distribution window.

3.2.1 Calculate difference of ln (lab result) from ln (target value)

Specimen Number	Target, mU/L (TV)	Lab Result, mU/L (LR)	ln(LR) - ln(TV) (Z)
H541	3.6	4.6	0.2451
H542	9.0	13.2	0.3829
H545	3.1	4.3	0.3272
H546	1.2	2.2	0.6061
H550	2.6	4.0	0.4307
H551	5.4	7.4	0.315
H552	2.5	3.2	0.2468
H553	5.2	7.9	0.4182
H554	4.3	5.1	0.1706
H555	6.4	7.5	0.1586
H556	2.6	N.R.	-
H557	6.5	7.6	0.1563
H558	5.2	7.3	0.3392
H559	4.4	5.9	0.2933
H560	5.7	8.4	0.3877
H561	6.2	6.6	0.0625
H562	6.0	7.0	0.1541
H563	5.0	6.2	0.2151
H564	2.4	2.7	0.1177
H565	4.2	4.2	0
H566	5.1	6.0	0.1625
H567	5.8	8.9	0.4281
H568	5.7	7.7	0.3007
H569	5.6	7.7	0.3184
H570	5.4	7.4	0.315

The target can be either the ALTM (as is the case for growth hormone in this example) or the appropriate GLTM (for example, for hCG).

The missing specimen numbers refer to specimens that were deemed unusable from the point of view of inclusion in the cumulative statistics. N.R. indicated that the lab did not return a result. Having obtained these differences (which are, as noted above, actually the logs of {result divided by target}), the calculation proceeds exactly as above.

3.2.2 Rank and trim deviations. Calculate mean (BIAS), LSD (GCV) and identify outliers

Z	Weight
0	Trimmed
0.0625	Trimmed
0.1177	-19
0.1541	-17
0.1563	-15
0.1586	-13
0.1625	-11
0.1706	-9
0.2151	-7
0.2451	-5
0.2468	-3
0.2933	-1
0.3007	1
0.315	3
0.315	5
0.3184	7
0.3272	9
0.3392	11
0.3829	13
0.3877	15
0.4182	17
0.4281	19
0.4307	Trimmed
0.6061	Trimmed

n = 24, k = 20
Proportion untrimmed, p = 0.8333
Unbiasing factor, b_p = 2.477

Mean of logs of trimmed values, $\bar{z}$

$$= \frac{\sum_{i=1}^{k} z}{k} = 0.2726$$

$$\text{BIAS} = (e^{\bar{z}} - 1) \times 100 = 31.3\%$$

$$k(k - 0.5) = 20 \times 19.5 = 390$$

$$LSD = \frac{b_p \times \sum_{i=1}^{k} (2i - k - 1) \times z_i}{k(k - 0.5)}$$

$$= 0.136$$

The GCV of the BIAS (the VAR) = $(e^{LSD} - 1) \times 100 = 14.6\%$

Limits for outliers are $(\bar{z} \pm 3\,\text{LSD})$ = (-0.351 to + 0.681)

So there are no within- laboratory, between- specimen outliers.

Therefore the laboratory cumulative performance in the six distribution window is described as

BIAS 31.3%

VAR 14.6%

No outlier results

Calculation of risk scores

(Maternal serum screening)

Protocol: Set of analyses that a laboratory uses to derive risk, e.g. “AFP and total hCG”, “AFP, free β-hCG and UE3”, etc.

Specimen statistics (At least five risk estimates are required to calculate these)

Target risk: The median of all risks returned on a given specimen by users of your protocol.

Non-parametric estimate of standard deviation (NPSD): This is the median of the absolute differences between each risk for a given protocol and the target risk. It is approximately 80% of the SD calculated in the usual fashion.

Non-parametric estimate of the coefficient of variation (NPCV): The NPSD expressed as a percentage of the target risk.

Laboratory statistics

Risk score (RS): Designed to be analogous to bias. Ideally, your RS should be zero. All risks on a given specimen for users of your protocol are arranged in order and divided into five bins, each covering 20 percentiles. Your RS is assigned according to which band your risk falls into:

Centile band	Risk score (RS)
< 20	-2
20 - 40	-1
> 40 - 60	0
> 60 - 80	+1
> 80	+2

Running risk score (RRS): Designed to be analogous to BIAS. It is the median of your risk scores recorded during the time window (most recent six distributions). Ten risk scores are needed to calculate RRS. Your RRS should be close to zero.

Non-parametric estimate of the SD of your RRS (SDRRS): Designed to be analogous to VAR. It is the non-parametric SD of your RRS. Calculated as the median of the absolute differences between your RS and RRS. Your SDRRS should be close to zero.

Calculation of qualitative scores

(Pregnancy testing)

Score (for a specimen)

Your reported result for each specimen is scored against the method group consensus and given a score of 0, 2 or 10 by reference to the following “look-up” table:

		Consensus result		
		N	E	P
Your result	N	0	2	10
	E	2	0	2
	P	10	2	0

Where “N” = Negative, “E” = Equivocal and “P” = Positive. For example, if the consensus result is “N” but your result is “P”, then your score is 10.

Cumulative interpretative score is calculated by the addition of your scores for each of the specimens in the current six distributions. At least six usable results are required.

Appendices

Conditions of participation in UK NEQAS (UK clinical laboratories)

BIAS and VAR performance criteria

Specialist Advisory Group membership

Steering Committee and Advisory Panel (NQAAP) membership

Useful addresses

Appendix 1

JOINT WORKING GROUP FOR QUALITY ASSURANCE: CONDITIONS OF EQA SCHEME PARTICIPATION (UK clinical laboratories)

Effective from October 2010

The Joint Working Group for Quality Assurance (JWG) is a multidisciplinary group accountable to the Royal College of Pathologists for the oversight of performance in external quality assurance schemes (EQA) in the UK. Membership consists of the Chairmen of the National Quality Assurance Advisory Panels (NQAAPs), and representatives from the Institute of Biomedical Sciences, the Independent Healthcare Sector, the Department of Health and the United Kingdom Accreditation Service (UKAS). The JWG has established the following conditions, that apply to any laboratory offering a service to patients in the United Kingdom directly or indirectly (e.g. by generating data for the Committee on Safety of Medicines or for medical research).

1. The Head of a laboratory is responsible for registering the laboratory with an appropriate accredited EQA scheme.

2. The laboratory should be registered with available EQA schemes to cover all the tests that the laboratory performs as a clinical service.

3. EQA samples must be treated in exactly the same way as clinical samples. If this is not possible because of the use of non-routine material for the EQA (such as photographs) they should still be given as near to routine treatment as possible.

4. Changes in the test methodology of the laboratory should be notified in writing to the appropriate scheme organiser and should be reflected in the EQA schemes with which the laboratory is registered.

5. Samples, reports and routine correspondence may be addressedto a named deputy, but correspondence from Organisers and NQAAPs concerning persistent poor performance (red - see below) will be send directly to the Head of the laboratory or, in the case of the independent healthcare sector, the Hospital Executive Director.

6. The EQA code number and name of the laboratory and the assessment of individual laboratory performance are confidential to the participant and will not be released by Scheme Organisers without the written permission of the Head of the laboratory to any third party other than the Chairman and members of the appropriate NQAAP and the Chairman and members of the JWG. The identity of a participant (name of laboratory and Head of Department) and the tests and EQA schemes for which that laboratory is registered (but not details of performance) may also be released by the Scheme Organiser on request to the Health Authority, Hospital Trust/Private Company in which the laboratory is situated after a written request has been received.

7. A NQAAP may, with the written permission of the Head of a laboratory, correspond with the Authority responsible for the laboratory, about deficiencies in staff or equipment which, in the opinion of the NQAAP members, prevent the laboratory from maintaining a satisfactory standard.

8. Laboratories' EQA performance will be graded using a traffic light system; green will indicate no concerns, amber poor performance, red persistent poor performance, with black being reserved for the tiny number of cases that cannot be managed by the Organiser or NQAAP and that have to be referred to the JWG. The criteria for poor performance (amber) and persistent poor performance (red) are proposed by the EQA scheme Steering Committee in consultation with the EQA Provider/Scheme Organiser and approved by the relevant NQAAP.

9. When a laboratory shows poor (amber) performance the Organiser will generally make contact with the participant in accordance with the Scheme Standard Operating Procedure for poor performance. Within two weeks of a laboratory being identified as a persistent poor performer (red) the Organiser will notify the Chairman of the appropriate NQAAP together with a résumé of remedial action taken or proposed. The identity of a persistently poorly performing laboratory (red) will be made available to members of the NQAAP and JWG. The NQAAP Chairman should agree in writing any remedial action to be taken and the timescale and responsibility for carrying this out; if appropriate this letter will be copied to accreditation/reregulate bodies such as UKAS and HFEA who may arrange an urgent visit to the laboratory. Advice is offered to the Head of the laboratory in writing or, if appropriate, a visit to the Laboratory from a NQAAP member or appropriate agreed expert may be arranged.

10. If persistent poor performance remains unresolved, the NQAAP Chairman will submit a report to the Chairman of the JWG giving details of the problem, its causes and the reasons for failure to achieve improvement. The Chairman of the JWG will consider the report and, if appropriate, seek specialist advice from a panel of experts from the appropriate professional bodies to advise him/her on this matter. The Chairman of the JWG will be empowered to arrange a site meeting of this panel of experts with the Head of the Department concerned. If such supportive action fails to resolve the problems and, with the agreement of the panel of experts, the Chairman of the JWG will inform the Chief Executive Officer, or nearest equivalent within the organisation of the Trust or Institution of the problem, the steps which have been taken to rectify it and, if it has been identified, the cause of the problem. The Chairman of the JWG also has direct access and responsibility to the Professional Standards Unit of the Royal College of Pathologists. Should these measures fail to resolve the issues, the laboratory will be referred to the Care Quality Commission for further action.

11. Problems relating to EQA Schemes, including complaints from participating laboratories, which cannot be resolved by the appropriate Organiser, Steering Committee or NQAAP, will be referred to the Chairman of the JWG.

Joint Working Group for Quality Assurance in Pathology, August 2010

Appendix 2

BIAS and VAR Performance Criteria [Reviewed March 2017]
(Subject to revision)

Scheme	Analytes	BIAS (+/-%)	VAR (%)
Peptide hormones I	FSH	20	15
	LH	20	15
	AMH	20	20
	Prolactin	20	15
	hGH	20	20
Peptide hormones II	PTH	25	25
	ACTH	25	25
	hCT	20	25
Tumour markers	AFP	10	10
	CEA	20	20
	hCG	20	20
Pregnancy testing	(Qualitative)	Interpretation score ≤10	
Maternal serum screening in the second trimester (concentrations and MoMs)	AFP	10	10
	Total hCG	10	10
	Free β-hCG	10	10
	UE3	20	15
	Inhibin-A	n.a.	n.a.
	Risk estimates	n.a.	n.a.
Maternal serum screening in the first trimester (concentrations and MoMs)	Free β-hCG	20	15
	PAPP-A	10	15
	Risk estimates	n.a.	n.a.

n.a., not assigned

Return Rate

Regular return of results is important, and failure to return results for three consecutive distributions constitutes poor performance.

Appendix 3

Specialist Advisory Group members

UK NEQAS Specialist Advisory Group for Immunoassay

Dr L Perry	Chairman
Dr G Wark	Secretary* and Organiser, UK NEQAS [Guildford]
Dr P Twomey	Panel Observer
Dr L Bailey	Expert member
Dr J Barth	Expert member
Professor S Ball	Expert member
Dr P Collinson	Expert member
Dr C Evans	Expert member
Dr J Ferguson	NIBSC liaison
Professor W Fraser	Expert member
Ms J French	Organiser, UK NEQAS [Birmingham]
Dr K Gordon	Expert member
Dr D Halsall	Expert member
Professor B Keevil	Expert member
Mr F MacKenzie	Director, UK NEQAS [Birmingham]
Dr L Owen	Expert member
Ms D Patel	Deputy Director, UK NEQAS [Sheffield]
Mr A Reid	Director, UK NEQAS [Glasgow]
Dr F Riddoch	Expert member
Professor M Strachan	Expert member
Dr C Sturgeon	Director, UK NEQAS [Edinburgh]

* Dr G Wark, SAS Peptide Section, Clinical Laboratory, Royal Surrey County Hospital, Egerton Road, Guildford, Surrey GU2 5XX.
Tel: +44 (0)1483 406715. E-mail: gwen.wark@nhs.net

UK NEQAS Specialist Advisory Group for Maternal Serum Screening

Prof K Spencer	Chairman
Dr R Clayton	FASP* liaison
Mrs K Donalson	Expert member
Dr C Evans	Expert member
Mr W Huttly	Expert member
Dr C Sturgeon	Director, UK NEQAS [Edinburgh]
Mr S Turner	Expert member
Professor D Wright	Director, DQASS**

* FASP, Foetal Anomaly Screening Programme; **DQASS, Down's Quality Assurance Advisory Service

Appendix 4

Steering Committee and National Quality Assurance Advisory Panel (NQAAP) members

UK NEQAS Steering Committee for Clinical Chemistry

Prof I Young (Chairman)	
Ms J French (Secretary)	Deputy Director, UK NEQAS [Birmingham]
Dr P Twomey	Panel Observer
Dr N Anderson	Expert member
Dr I Barnes	Pathology Quality Assurance Review liaison
Dr W Bartlett	Expert member
Ms R Carling	Chair, SAG for Paediatric Investigations
Dr P Cook	Chair, SAG for Trace Elements
Dr J Forsyth	Chair, SAG for Clinical Chemistry
Mr I Hanning	Expert member
Dr A-M Kelly	Chair, SAG for Interpretative Comments
Ms Z Khatami	Expert member
Mr F MacKenzie	Director, UK NEQAS [Birmingham]
Dr L Perry	Chair, SAG for Immunoassay
Mr A Reid	Director, UK NEQAS for Cardiac Markers
Dr J Sheldon	Scientific Advisor, Proteins
Dr C Sturgeon	Director, UK NEQAS [Edinburgh]

* SAG, UK NEQAS Specialist Advisory Group

National Quality Assurance Advisory Panel (NQAAP) for Chemical Pathology

Dr B Lopez	Chair
Dr I Bailey	
Dr L Ford	
Dr D James	
Dr W Simpson	
Dr R Still	
Dr P Twomey	

Appendix 5

Useful addresses

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National Institute for Biological Standards and Control	NIBSC 5 Blanche Lane Potters Bar Hertfordshire, EN6 3QG Tel: +44 (0) 1707 641000 Fax: +44 (0) 1707 641050 E-mail: enquiries@nibsc.org www.nibsc.org/

UK NEQAS [Edinburgh] website: www.edqas.org