UK NEQAS
Guildford Peptide Hormones

Participant's Handbook

UK NEQAS Guildford Peptide Hormones

SAS Trace Elements Centre

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Contents

1.0 Service Provided and Scheme Background and Aims

Scheme	Analytes
Peptide Hormones	Insulin and C-Peptide Gastrin IGF-I and IGFBP-3

The UK NEQAS Guildford Peptide Hormones Scheme has been running for over 40 years and assists participants in monitoring the hormones regulating glucose metabolism, growth and gastric function.

The scheme was established in 1975 with the distribution of samples to United Kingdom hospital laboratories measuring insulin and gastrin. This work was initiated and funded by the Supra-Regional Assay Service (SAS) Peptide Hormone Laboratory, which was part of the Department of Clinical Biochemistry and Clinical Nutrition, St. Luke's Hospital, Guildford, Surrey. During the next 10 years participation in the scheme expanded and in 1983 the scheme was extended to include C-peptide. In the 1990s the use of Insulin-like Growth Factor-1 (IGF-I) and Insulin-Like Growth Factor Binding Protein 3 (IGFBP-3) as clinical diagnostic tools were becoming more widespread and the scheme added these analytes to its repertoire.

In 1996 the laboratory moved to new premises within the Royal Surrey Hospital and continues to work from there today, maintaining a close link with the clinical laboratory to facilitate appropriate specimen collections and maintain methodological updates.

In 1998 the scheme joined the UK NEQAS organisation as an associate scheme. By linking with UK NEQAS there is a formal mechanism for external oversight and additional scientific advice to be provided for the scheme. The aims of the Guildford Peptide Hormones Scheme, which are consistent with those of UK NEQAS, are to:

- Provide professionally led and scientifically based schemes with a primarily educational objective
- Provide regular distributions of specimens
- Provide rapid feedback of performance
- Support participants where problems occur and stimulate the overall improvement in performance among all participating laboratories

In order to meet these objectives, lyophilised human-based samples for insulin, C-peptide, IGF-I, gastrin and IGFBP-3 are distributed every six weeks. Reports contain critical information about bias, reproducibility and, with occasional samples, recovery of added analyte. This is achieved with the use of International Reference Preparations (IRPs) and International

Standards (IS), if they are not available, human recombinant materials. Selected distributions may also contain laboratory surveys or interpretative exercises to highlight current laboratory practice.

2.0 Address and Communications

UK NEQAS Guildford Peptide Hormones
SAS Trace Elements Centre,
Surrey Research Park
15 Frederick Sanger Road
Guildford, Surrey
GU2 7YD
United Kingdom

Telephone: +44(0)1483 689022
Email: rsch.peptideeqa@nhs.net
Website: www.surreyeqas.org.uk

The website for reporting a result is www.birminghamquality.org.uk

Please quote your laboratory code number in all communications with the Scheme. If no response is received within 5 working days please make contact again as the email communication may have been lost.

The telephone is staffed between 0900 and 1700 Monday to Friday with an answer machine to pick up messages outside these times. Participants will be asked to give their laboratory code number when contacting the centre and will be asked the nature of their enquiry to allow their call to be transferred to the appropriate member of staff. All calls and the actions taken are logged.

A website for the UK NEQAS organisation and which also gives specific information for other UK NEQAS Centres and Schemes, including Guildford Peptide Hormones is at www.ukneqas.org.uk

3.0 Staffing

Dr Gwen Wark **Scheme Director**	Tel: +44(0)1483 406715 Email: gwen.wark@nhs.net
Dr Chris Harrington **Deputy Scheme Director**	Tel. +44(0)1483 689977 Email: chris.harrington1@nhs.net
Mr Godwin Tetteh **Scheme Manager**	Tel: +44(0)1483 689978 Email: godwin.tetteh@nhs.net
Mr Stuart Kerr **Medical Technical Officer 2**	Tel: +44(0)1483 689022 Email: stuart.kerr4@nhs.net
Ms Bahareh Jafari Medical Laboratory Assistant	Tel: +44(0)1483 689022 Email: bahareh.jafari@nhs.net
Ms Sarah-Jane Bainbridge **EQA Quality Manager**	Tel: +44(0)1483 689022 Email: sbainbridge1@nhs.net

4.0 External Regulation of our Services

4.1 Accreditation

The scheme is recognised by the UK NEQAS consortium and operates in accordance with the UK NEQAS Code of Practice (see www.ukneqas.org.uk). Accreditation is undertaken by United Kingdom Accreditation Service (UKAS) according to "ISO 17043:2010 Conformity assessment — General requirements for proficiency testing". The first inspection is expected to take place in 2020.

4.2 UK NEQAS Consortium

The scheme has close ties with other UK NEQAS operations though the UK NEQAS Consortium. All UK NEQAS-designated services comply fully with the UK NEQAS Code of Practice.

4.3 Steering Committees & Specialist Advisory Groups

All EQA providers are required to seek advice from and report to Steering Committees and/or Specialist Advisory Groups. The Clinical Chemistry division of UK NEQAS is presently served by an overall Steering Committee (SC) which advises on overall policy matters, with Specialist Advisory Groups (SAGs) providing external scientific advice.

4.4 National Quality Assurance Advisory Panels

All full UK NEQAS schemes report to the National Quality Assurance Advisory Panel (NQAAP) for Chemical Pathology. The names of SC, SAG and Panel Chairs and Secretaries are available on the UK NEQAS website for any participants who wish to express comments or concerns about schemes and their operation.

5.0 Enrolment and Charges

Prospective participants should contact the scheme by phone or email at the contact details given above for a copy of the current registration form which includes details of the fees for participation.

The scheme's calendar year runs from April to March, although participants are able to register at any time of the year on a pro-rata basis. Participation begins at the first distribution following receipt of completed forms.

Although the majority of participants are diagnostic service laboratories, all laboratories are welcome to join. This includes non-UK, research and in vitro diagnostic medical devices (IVD) manufacturers' laboratories. For UK clinical service laboratories, the act of enrolling in a scheme confirms their willingness to be bound additionally by the current Joint Working Group (JWG) Conditions of Participation. The terms and conditions, and other information about the Joint Working Group can be accessed via the link below:

https://rcpath.org/profession/committees/jwgqa.html

Participation of non-UK laboratories may be subject to the availability of suitable specimen transport. Manufacturers may participate on an 'information only' basis, i.e. without receiving samples and returning results. They may also register methods under development on an anonymous basis.

Between January and March of each year, participants are sent a registration form and requested to confirm or amend their registration details for the following year.

Please inform the scheme immediately if there are any changes to your registration details at any time throughout the scheme year.

If you wish to cancel your participation in the scheme, please notify the scheme in written form. Temporary suspension in the scheme can apply, e.g. if your laboratory is no longer offering the test as a clinical service, provided that the scheme is notified in writing. Failure to provide payment for enrolment in the scheme will result in the cancellation of registration.

The scale of charges is published annually and is available on request. The charging period is 1st April to 31st March, or pro-rata for part year participation. EQA services are run according to the not-for-profit terms of the UK NEQAS Code of Practice. Changes to charges are implemented only after approval by the UK NEQAS Board of Directors.

6.0 Scheme Organisation

6.1 Laboratory code numbers

Participants are assigned a unique laboratory code number, which is common across a number of UK NEQAS schemes. A participant will be assigned an additional laboratory number if more than one result is returned for a single analyte. This may occur if more than one instrument is used for a particular analyte, or if the participant is evaluating a different method in addition to the established method.

6.2 Method codes

Methods are normally referred to by full name, but occasionally a code is used where space is limited on the printed page. Please check your method is up to date and inform us of any changes.

6.3 Confidentiality

The participation, raw data and performance scores 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 (see section 5.0 Enrolment and Charges) as part of the routine reporting of persistent poor performance. These data may be shared with local management, regional QA officers, accrediting bodies and suppliers of equipment and reagents where appropriate and necessary, *but only with the participant's permission*. Reports are copyright and may not be copied, distributed, published or used for publicity and promotion in any form without written consent of the Scheme Director on each and every occasion. However, performance data may be shared with individual client's e.g. GP's without consultation with the Scheme Director.

7.0 Scheme Operation

7.1 Specimens

Specimens are obtained from three sources; human volunteers, from residual clinical specimen materials, or from commercially purchased human serum.

Specimens may be "spiked" with standards or other source of analyte, or with another analyte(s) to test method performance. 1 mL aliquots of the sample pools are lyophilised and stored at 4°C prior to issue. No preservative is added to the lyophilised pools. Specimens are distributed at ambient temperature. Specimens must be reconstituted with 1 mL of distilled or deionised water and mixed for 15 minutes before analysis by participants.

Several analytes share a common sample. The sample pools are prepared with:

- Insulin and C-Peptide
- Gastrin
- IGF-I and IGFBP-3

Therefore a laboratory that is registered for insulin, C-peptide and IGF-I will receive 2 sample sets.

The specimens are provided solely for the purposes of EQA. Residual material may be retained by participants for method evaluations. However it is recommended that fresh samples are obtained from the scheme for such evaluations.

If specimens are to be used in research which is expected to be published, written consent must be obtained from the Scheme Director on each and every occasion.

Safety precautions in handling specimens

The clinical materials used to produce the EQA samples are screened for COVID-19 prior to sample production. However as for all clinical material, EQA samples should be handled as if being capable of transmitting infections. The same health and safety precautions which are normally adopted in the handling of patient specimens should be used during EQA sample receipt, storage, preparation for analysis, and their eventual disposal.

7.2 Schedule of specimen and report distribution

Specimens are distributed every 6 weeks together with a form for reporting results to the registered scheme contact. In the UK, first class mail is used. For overseas participants, packages are posted by airmail with an express surcharge (if necessary). A schedule of specimen despatch dates is provided each year and available on the UK NEQAS Birmingham Quality website (www.birminghamquality.org.uk). Participants should contact the scheme at the contact details given in section 2.0 if specimens are not received within 7 working days of the distribution despatch date.

Sample packaging complies with current UN3373 requirements for the postage of clinical material.

Interim reports from the previous distribution are sent out following the closing date for the distribution. These reports should be received by participants within 5 working days of the result return deadline. The final reports are made available approximately 6 weeks later with

the interim reports of the following distribution. Please contact the scheme if reports have not been received within this time period. The scheme is also due to introduce Network Reports in early 2021. These reports will allow users with multiple participant numbers (multiple analysers performing the same tests) to easily compare instrument performance on one combined report as well as allowing access to the normal instrument specific reports from a single centralised login. Please enquire by email if this is a service you would be interested in utilising.

8.0 Processing UK NEQAS Specimens

8.1 Receipt and analysis

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

It is recommended that if an assay is not to be performed on the day of receipt the lyophilised specimens should be stored at 4°C.

Specimens must be reconstituted with 1mL of distilled or deionised water and mixed for 15 minutes before analysis.

If reconstituted samples are required for further analysis, the samples should be stored frozen.

UK NEQAS samples are intended to monitor your performance for routine patient specimens, so please process them through your normal reception, analytical and reporting procedures.

In order to meet this goal, the following guidelines should be met:

- EQA samples should be labelled in the same manner as a patient sample – it should not be known by the analysts to be an EQA sample.
- Instrument calibration, routine maintenance, and other assay parameters should be done with no greater frequency for EQA samples than for patient samples.
- EQA samples should be run the same number of times as a patient sample – it should not be run multiple times UNLESS a patient sample is run multiple times under the same circumstances. If it is desired to run replicate determinations of the EQA sample, the results should be returned BEFORE the additional replicate assays are performed.
- Results below the minimum detection level should be reported to show the limit of detection.

By adhering to these guidelines, the efficacy of external quality assessment is maximised.

8.2 Return of results

Results must be submitted by the closing date on the return form.

In the first instance results should be returned using the password-protected website facility: www.birminghamquality.org.uk. Following enrolment with the scheme, participants will be issued with a username, password and instructions to access the website. Where access to the website is not possible results may be returned by post or email to the Scheme's email address (rsch.peptideeqa@nhs.net). Please ensure results and decimal points are written clearly on the return sheet as there can be a loss of clarity when scanned. **Please indicate clearly on the return sheet if your units differ from those shown.**

9.0 Performance Assessment

9.1 Failure to return results

If you do not return any results for a distribution by the due date you will still receive a report. However, regular participation is essential if appropriate method performance data is to be obtained and is part of the criteria for good performance.

If results are not returned for a distribution, you will be regarded as having poor performance and it will be noted on your report when issued.

If you are unable to return results on a distribution please contact the scheme as soon as possible with an explanation of the reason for not doing so.

9.2 Target values

UK NEQAS Guildford Peptide Hormones 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 achieve for peptide hormones, where reference methods are largely unavailable. UK NEQAS Guildford Peptide Hormones aims to meet minimum validity criteria by testing recovery, linearity and stability of the targets at regular intervals throughout the year. Wherever possible the all-laboratory trimmed mean (ALTM) is used as the target.

9.3 Introduction to analytical performance scores

'ABC of EQA' is an ISO 17043:2010 compliant framework for the assessment of a laboratories analytical performance in a particular assay which meets and surpasses the utility of existing systems. The main benefit for participants, EQA Organisers, Steering Committees, Specialist

Advisory Groups and the NQA Advisory Panels alike, is that it is a single system, which can allow meaningful comparisons to be made between analytes, schemes and disciplines.

The reports for the UK NEQAS Guildford Peptide Hormone' scheme are structured to best utilise the 'ABC of EQA' scoring system, so you are able to see at a glance if your laboratory is performing well. If performance is acceptable, no further action is required. If performance is poor, you can probe further into the data presented. Similarly, you can see if you are performing in keeping with other users of your method and whether the method itself is performing well.

Definitions

There are three scores A, B and C

A is for Accuracy (total error)

B is for Bias

C is for Consistency of bias

They are conveniently referred to as the 'A score', 'B score' and 'C score', or simply A, B and C. Every laboratory in the scheme will have an A, B and C score for each analyte they measure and all 3 should be used when reviewing performance. Each of the 3 scores is calculated over a rolling time-window and thus comprises results from many specimens. They are always being updated with fresh current data, while older data drops out of the 'time-window'. The time-window has been set at 6 distributions. One of the main purposes of a performance score derived from many samples is to 'smooth out' the natural variation in deviations from target values over a number of distributions, by trimming extreme values and deriving a robust estimate of the central tendency for overall bias together with an index of its consistency. Thus when interpreting the performance score elements of reports, it is important to note that a small number of atypical results are unlikely to affect overall scores, and aberrant results which are numerous enough to affect performance scores will take time to work their way out of the scoring 'window'.

For all UK NEQAS centres, a low score is 'good', a high score is 'bad'.

The A Score **Accuracy**

The A score is weighted as part of a transformation process to take into account factors such as 'degree of difficulty' and normalised (median set at 100). The A score is primarily used as a quick 'comparator' or 'screening tool' for performance across all analytes. An A score of '100 is

'average', but this may of course be 'better' or 'worse' than what is required clinically, depending on the analyte. As more UK NEQAS schemes adopt the 'ABC of EQA' approach, the more useful the A score becomes in allowing broad comparisons to be made between analytes.

The A score tells you, on average, how good your overall performance is. This takes into account such factors as bias, consistency of bias, degree of difficulty etc. It has been transformed to ensure that A scores are broadly equivalent across analytes. For example, if you have an A score of 85 for Insulin and you also have an A score of 85 for Gastrin, this would indicate that you are performing both, on average, equally well.

The A score is an estimate of accuracy [total error] and is derived by taking the Specimen % bias and transforming it by a 'degree of difficulty' factor (see below) to get a Specimen transformed bias [this can be positive or negative]. The modulus of this Specimen transformed bias is then taken to give the Specimen Accuracy Index [as it is a modulus it has no sign]. Finally, the 'A score' is calculated as the trimmed mean of all of the Specimen Accuracy Indices in the rolling time-window.

Because the A score is an across-analyte comparator, the limits used for the A score are common across all analytes, namely:

Up to and including 100 (green on report)

From 101 up to and including 200 (yellow on report)

Greater than 200 is (red on report)

Degree of difficulty factor: The transformation itself has been empirically derived separately for each analyte and is based on modelling of data dependent on the concentration (target value) for the individual specimen. An examination of the relationship between CV and target value for the analyte was conducted to derive an equation for this relationship. This yielded the concentration-dependent factors used. Normalisation of the factors to yield a median (average participant) A score of 100 was then carried out.

The B and C Scores **Bias and Consistency**

The B and C scores (which have not been transformed) should be looked at together and provide analytical data on average bias and its consistency (pattern). The B score is Bias and therefore shows, on average (across the 6 distribution window), how far from the target results are and if results are running high or low.

The Consistency of bias or C score indicates, on average, if you usually have the same bias pattern. It is also not transformed and can assist in answering the following questions. 'Do you have different bias depending on the concentration of analyte in the sample?' 'Does your bias vary depending on the specimen matrix?' 'Has your bias changed during the time window?' 'Are you imprecise?'

A high (poor) C score does not necessarily mean that you are imprecise, though if you are imprecise, it is impossible for you to have a very good (low) C score. Poor consistency of bias is not the same as imprecision. The 'C score' is simply the standard deviation (adjusted to take into account the degree of trimming) of the data which make up the B score.

9.4 Calculation of analytical performance scores

A Score:

When calculating the A score, the Specimen Bias for each sample in the 6 distribution window is calculated. The equation for this is given below:

$$Specimen\ Bias\ (\%) = \frac{Result - Target}{Target} \times 100$$

The Specimen Biases are the each divided by the appropriate Degree of Difficulty:

$$Specimen\ Transformed\ Bias = \frac{Specimen\ Bias\ (\%)}{Degree\ of\ Difficulty}$$

Using this, the Specimen Accuracy Index is found.

$$Specimen\ Accuracy\ Index = Modulus\ of Specimen\ Transformed\ Bias$$

The trimmed mean of the specimen accuracy indices gives the A score.

B Score

The B score is the average (trimmed mean) Specimen Bias across the 6 distribution window. The equation for the Specimen Bias is given below:

$$Specimen\ Bias\ (\%) = \frac{Result - Target}{Target} \times 100$$

C Score

The C score is the standard deviation of the biases cross the 6 distribution window.

The Scheme Director / Manager may exclude certain sample pools and/or methods from the calculation of target values and scoring if these are atypical or may unduly affect apparent assay performance. These actions may be performed in consultation with the Specialist Advisory Group (SAG) for Endocrinology and Immunoassay.

The Standard Uncertainty

The Standard Uncertainty (SU) statistic has now been added into our reports. The inclusion of this statistic is a requirement for UKAS ISO17043:2010 Accreditation. The SU can be found to the right of the histograms.

The SU is calculated as 1.25*[SD/SQRT n]. The 'n' used in this calculation relates to a post trimming value (where appropriate) not the 'n' value listed on reports. The target is considered valid if 'u' is less than 0.3*SD. It is our reading of the algebra that, when you re-arrange the equations, if n<18 it is impossible to pass.

9.5 Late results

We will accept late returns to the interim reports but once the final reports are published, late results can only be accepted in limited situations. All amendments to interim or final reports are made at the discretion of the Scheme Director / Manager.

9.6 Blunders and their correction

Blunders are defined as errors, which may or may not be detected as outliers, and a record is kept by the scheme of each incident. Participants are allowed one blunder per scheme year, depending on the circumstances and risk, they may be considered poor performance. Blunders may be due to:

- assaying the wrong samples
- assaying the right samples in the wrong order
- incorrectly transcribing laboratory results from computer systems or worksheets to the results document
- use of incorrect units and/or conversion factors
- technical errors e.g. incomplete mixing after thawing, faulty sampling/pipetting, incorrect preparation of calibration solutions etc.

Such errors will be corrected in most circumstances, so that they do not confuse the underlying assay performance. However, the fact that blunders have occurred will be

recorded separately. Amended reports will be given a unique identification with reference to the original report and include a statement concerning the reason for the amendment.

9.6.1 Amendment prior to reporting deadline

For Amendments prior to the reporting deadline, amended copies of already entered results should be clearly marked “Amended results” with the change unambiguously highlighted and returned to us by email.

9.6.2 Amendments after the reporting deadline

Please email us to explain the problem. Results can be amended prior to the publication of the interim reports.

Once interim reports have been published, amendments should be requested in writing (by email) with an explanation for the reason for any amendment. All amendments are made at the discretion of the Scheme Manager or Director.

Where investigation reveals the cause of the error and repeat results are available, correction of the original results is permissible. A copy or screenshot of the experiment with evidence of the results and analysis date will be requested. However, the fact that incorrect results were reported will be recorded as a blunder.

Once a final report has been issued, amendments to results will not be accepted useless exceptional circumstances can be demonstrated. As before, these amendments are made at the discretion of the Scheme Manager or Director.

9.6.3 Amendments after the receipt of reports

These should be reported in writing with an explanation of the reason for any amendment. Please include a description of how patient samples are run in your laboratory giving particular attention to the area that caused the blunder, e.g. how your results are reported if the blunder was caused by a transcription error. Changes can be made only in those cases where the error is an artefact of running the EQA samples differently to patient samples. If at all possible, EQA samples should be processed exactly the same way as patient samples from labelling to sending the results back on the normal laboratory results forms. Errors caused by sample mislabelling cannot be corrected because a similar error could be made on patient samples. Where investigation reveals the cause of the error, and repeat results are available, correction

of the original results may be permissible. However the fact that you reported incorrect results will be recorded and reviewed annually.

9.7 UK NEQAS Guildford Peptide Hormones errors

If you suspect that we have made an error please let us know immediately. We audit all such errors and it is important that we know about them so that we can improve our service. Errors made by UK NEQAS Guildford Peptide Hormones will be corrected and amended reports will be provided. Any penalties incurred by the laboratory will be removed.

10. Performance Criteria

Limits for acceptable performance are recommended by the Scheme Director and endorsed by the National Quality Assurance Advisory Panel (NQAAP), after consultation with the schemes and Specialist Advisory Group (SAG), to reflect clinical requirements, the state of the art analysis and the need for regular Quality Assurance monitoring. The criteria include acceptable limits for the B and C scores, and for return rate. These are summarised in Appendix A Limits of Acceptable Performance.

The 6-weekly reports include figures to show your performance in relation to these criteria. Laboratories should aim to maintain performance within these limits and are invited to contact the Scheme if problems appear to be developing, whether in analytical performance or in their ability to maintain return rates.

10.1 Persistent poor performance and action taken

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

- their B and/ or C scores are outside the performance criteria for three consecutive distributions

  Or if
- it fails to return results for three distributions in 8 month period, without notifying the UK NEQAS Centre of a change in participation.

UK NEQAS Guildford Peptide Hormones is required to report to the NQAAP for Chemical Pathology any laboratory performance that is persistently unacceptable.

The Scheme Director will make informal contact with any participant falling into the above categories inviting them to discuss action to correct the poor performance. If a satisfactory

response is received and improvement in performance ensues, no further action will be taken. If no response is received or performance fails to improve then the Director will notify the Chairman of the appropriate NQAAP. Advice is then offered to the Head of the laboratory in writing or, where appropriate and very rarely, following a visit to the laboratory from a NQAAP member, or appropriate expert (if agreed).

If poor performance is due to the method used, such that all method users have a large negative or positive bias, the Scheme Director will contact the assay manufacturer and work directly with them to solve the issues with the assay.

11. Past UK NEQAS Specimens

We can usually provide aliquots of previously issued specimens with target values for laboratories wishing to check existing assays or to evaluate new ones. An additional charge may be made for these specimens.

12. Scheme Development & Scientific Support

External scientific advice is provided by the Specialist Advisory Group (SAG) for Endocrinology and Immunoassay. The SAG reports to the UK NEQAS Steering Committee for Clinical Chemistry which co-ordinates UK NEQAS policy and provides strategic direction.

The scheme reports to the National Quality Assurance Advisory Panel (NQAAP) for Chemical Pathology. We are required to report those participants whose performance scores are outside the set limits on a number of occasions or who fail to return sufficient results. The details of the SAG and Steering Committee are available from the UK NEQAS Office while the list of NQAAP panel members is available on the RCPath website via the link below:

https://rcpath.org/profession/committees/jwgqa.html.

13. Comments, Complaints and Appeals

If you have any comments or complaints about any aspect of the scheme, whether scientific or operational, or wish to appeal against assessment of performance, please contact the scheme. The Scheme Director and/or Scheme Manager will follow up on the initial response with a thorough investigation and is ultimately responsible for ensuring that appropriate corrective action has been taken.

Complaints should be in the form of letter or email. The on-line results document includes a section in which participants may include comments or remarks for the attention of the organisers. While these will generally refer to the samples or to analytical difficulties

experienced by the participant any observation, at any time, is welcomed. Please use your laboratory code number in all correspondence and provide details of the distribution date and specimen numbers wherever possible.

A formal complaints procedure is in place and wherever possible will be actioned internally. We will endeavour to rectify problems as soon as possible. If the problem cannot be resolved it will be referred to the Chair of the Joint Working Group on Quality Assurance.

Participants may prefer to address comments or complaints, including an appeal against assessment of performance, to any member of the UK NEQAS Specialist Advisory Group for Endocrinology and Immunoassay, the Steering Committee for Clinical Chemistry or the National Quality Assurance Advisory Panel for Chemical Pathology.

14. Subcontracted Services

Various aspects of the proficiency test scheme can from time to time be sub-contracted. When sub-contracting occurs it is placed with a competent sub-contractor and the proficiency testing provider is responsible for this work.

15. Changes to Scheme Design

In the event that changes are made to the Scheme, participants will be informed promptly either in writing as a letter posted with the next distribution of samples or by email to the identified contact personnel given on the participant's registration form.

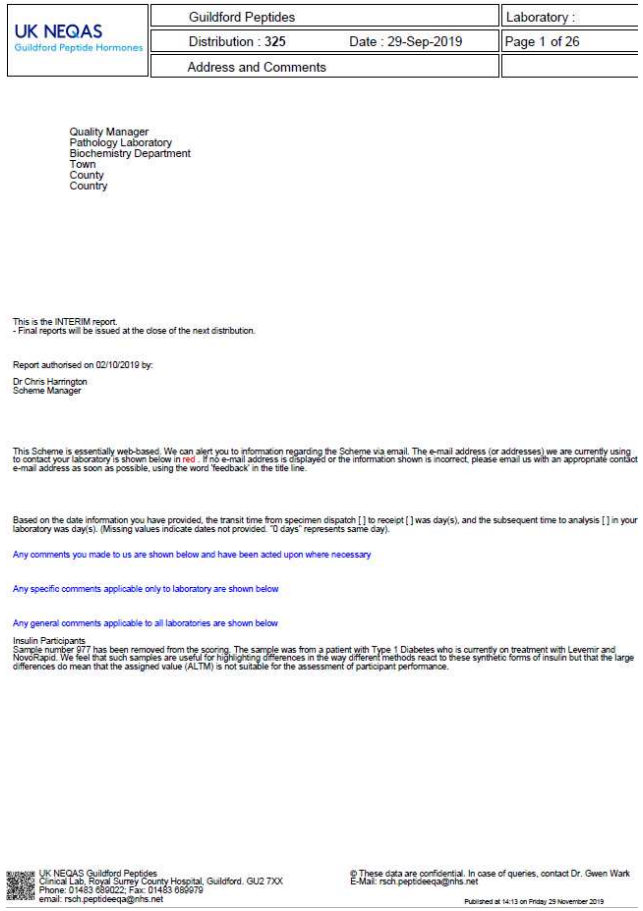
16. Terminology

ALTM	The All Laboratory Trimmed Mean, which is the geometric mean of the entire set of trimmed results for a specimen.
Bias	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.
Pool	A bulk preparation of serum usually prepared from several individual donations and of defined characteristics.
Sample/ Specimen	An aliquot of a given **pool**. The same pool may be issued on two or more occasions as different specimens.
SAG	Specialist Advisory Group.
Scoring	The 3 values per analyte which provide an overview of your performance. The scores are the A, B and C scores. More information regarding how they are calculated and how they should be interpreted is available in section 9.
Target Value	The scheme uses the ALTM (see above) to establish the target value.
Transformation	The A score is the only transformed score used to assess participant performance. This is done by dividing the Specimen Bias by the appropriate value for the Degree of Difficulty. This means that this score takes into account how difficult the assay is to perform and how difficult it is at that particular sample concentration before the score is calculated.
Trimming	The effect of aberrant results that may be present is minimised prior to statistical analysis. The chosen method is that of 10% Healy, which involves trimming the lowest and highest 10% of results on datasets where n>4. Note that trimmed results are not necessarily outliers**.**

Unusable Specimen	Unusable specimens include those with analyte concentration near the detection limits of the assay, those with added interfering substances or those deemed to not be homogenous. In some circumstances, unusable specimens may be issued by the scheme but will be removed from the scoring and therefore will not be used to assess performance. These samples are for education purposes only and are used to highlight methodological differences.
Usable Specimen	A specimen that has no unusual or unacceptable features will be deemed to be usable for the calculation of ABC scores.

17. Distribution Reports

Cover Page



UK NEQAS Guildford Peptide Hormones

Guildford Peptides | Laboratory :
Distribution : 325 Date : 29-Sep-2019 | Page 1 of 26
Address and Comments

Quality Manager
Pathology Laboratory
Biochemistry Department
Town
County
Country

This is the INTERIM report.
- Final reports will be issued at the close of the next distribution.

Report authorised on 02/10/2019 by:

Dr Chris Harrington
Scheme Manager

This Scheme is essentially web-based. We can alert you to information regarding the Scheme via email. The e-mail address (or addresses) we are currently using to contact your laboratory is shown below in red . If no e-mail address is displayed or the information shown is incorrect, please email us with an appropriate contact e-mail address as soon as possible, using the word 'feedback' in the title line.

Based on the date information you have provided, the transit time from specimen dispatch [ ] to receipt [ ] was day(s), and the subsequent time to analysis [ ] in your laboratory was day(s). (Missing values indicate dates not provided. "0 days" represents same day).

Any comments you made to us are shown below and have been acted upon where necessary

Any specific comments applicable only to laboratory are shown below

Any general comments applicable to all laboratories are shown below

Insulin Participants
Sample number 977 has been removed from the scoring. The sample was from a patient with Type 1 Diabetes who is currently on treatment with Levemir and NovoRapid. We feel that such samples are useful for highlighting differences in the way different methods react to these synthetic forms of insulin but that the large differences do mean that the assigned value (ALTM) is not suitable for the assessment of participant performance.

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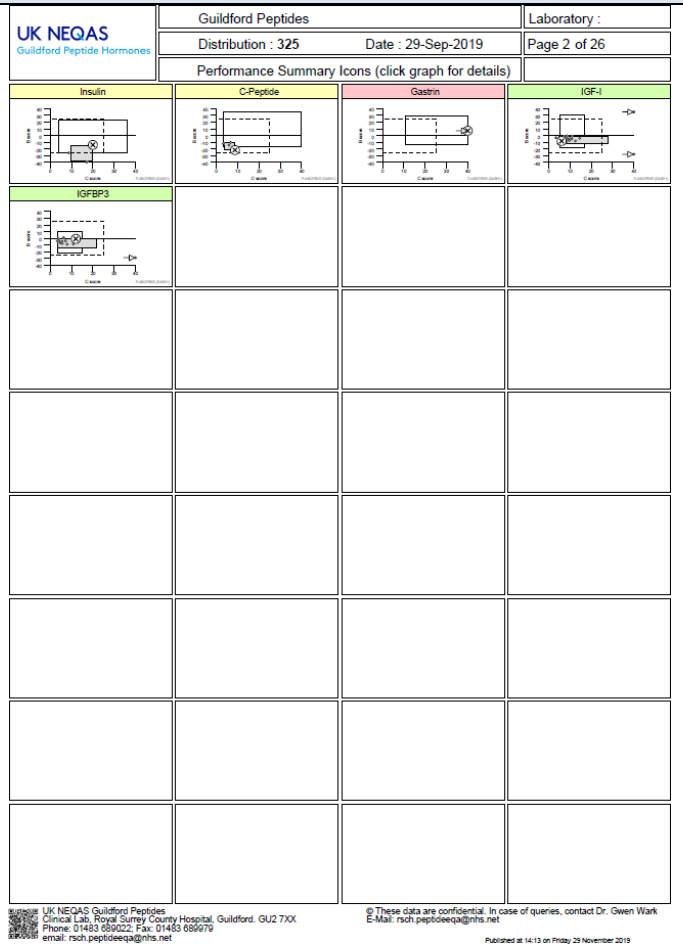
The front page identifies the distribution and the participant. It shows the contact details the scheme has for the participant so they can ensure they are up to date in our system. Comments left by and for the participant are also shown here.

Performance Summary



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Distribution : 325 Date : 29-Sep-2019 | Page 2 of 26
Performance Summary Icons (click graph for details)

Insulin | C-Peptide | Gastrin | IGF-I
IGFBP3

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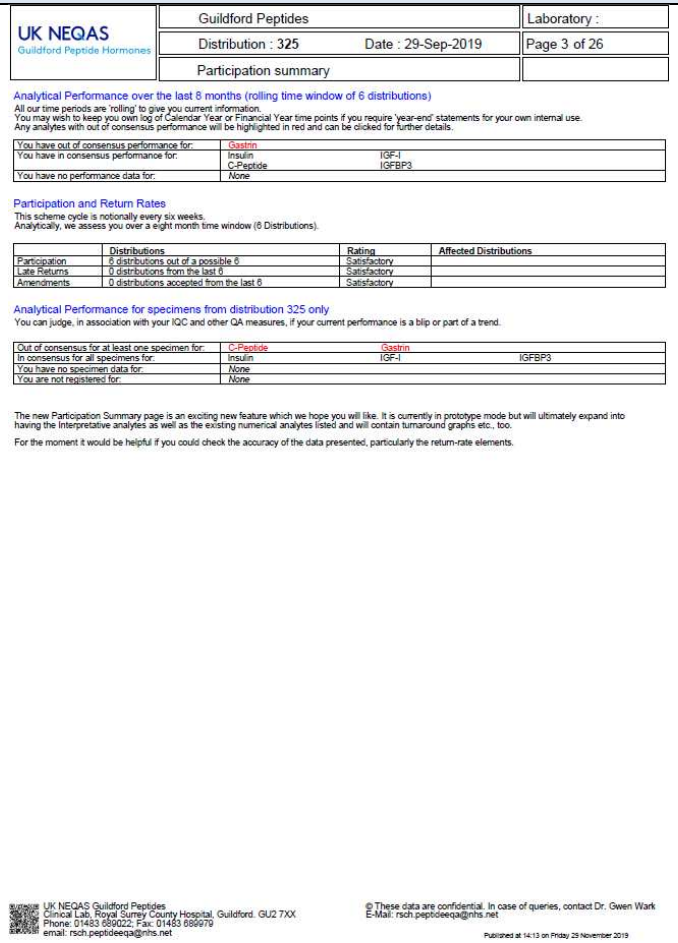
This is a quick summary of the analytes you are registered for. Analytes are colour coded to highlight those which are outside performance limits. The penalty box plots show how you compare with other users of your method and others. There are also links to the analyte pages; simply click on a graph to be taken to that page.

Participation Summary



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Distribution : 325 Date : 29-Sep-2019 | Page 3 of 26
Participation summary

Analytical Performance over the last 8 months (rolling time window of 6 distributions)

All our time periods are 'rolling' to give you current information.
You may wish to keep you own log of Calendar Year or Financial Year time points if you require 'year-end' statements for your own internal use.
Any analytes with out of consensus performance will be highlighted in red and can be clicked for further details.

You have out of consensus performance for:	Gastrin	
You have in consensus performance for:	Insulin C-Peptide	IGF-I IGFBP3
You have no performance data for:	None	

Participation and Return Rates

This scheme cycle is notionally every six weeks.
Analytically, we assess you over a eight month time window (6 Distributions).

	Distributions	Rating	Affected Distributions
Participation	6 distributions out of a possible 6	Satisfactory	
Late Returns	0 distributions from the last 6	Satisfactory	
Amendments	0 distributions accepted from the last 8	Satisfactory	

Analytical Performance for specimens from distribution 325 only

You can judge, in association with your IQC and other QA measures, if your current performance is a blip or part of a trend.

Out of consensus for at least one specimen for:	C-Peptide	Gastrin	
In consensus for all specimens for:	Insulin	IGF-I	IGFBP3
You have no specimen data for:	None		
You are not registered for:	None		

The new Participation Summary page is an exciting new feature which we hope you will like. It is currently in prototype mode but will ultimately expand into having the Interpretative analytes as well as the existing numerical analytes listed and will contain turnaround graphs etc., too.

For the moment it would be helpful if you could check the accuracy of the data presented, particularly the return-rate elements.

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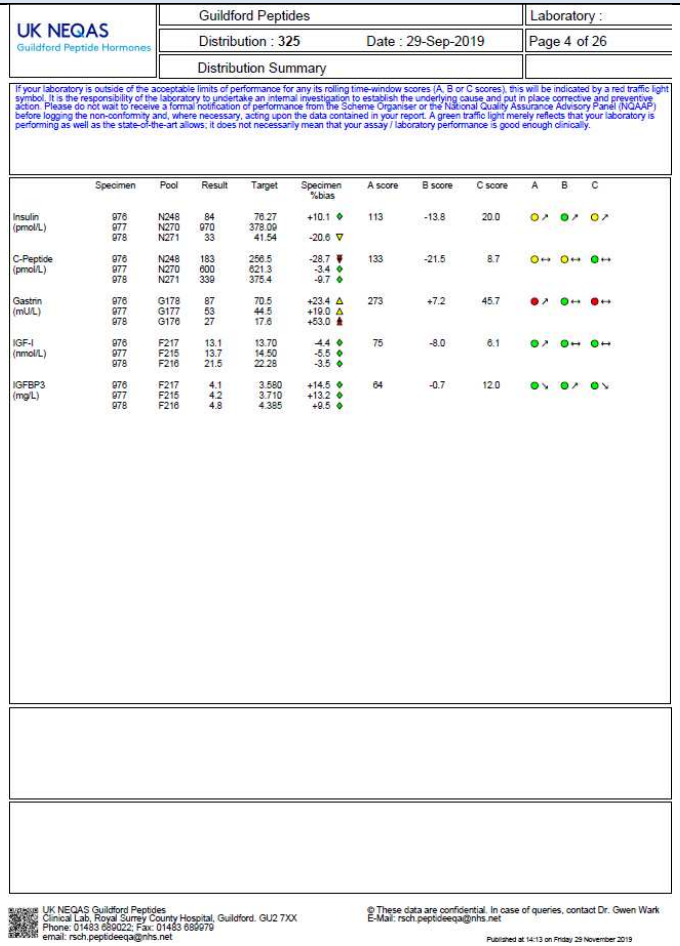
This is an overview of your average and current performance for each analyte in addition to a record of how many distributions you have returned results for, how often your results were late and how many amendments you have required over the last 8 months.

Distribution Summary



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Distribution : 325 Date : 29-Sep-2019 | Page 4 of 26
Distribution Summary

If your laboratory is outside of the acceptable limits of performance for any its rolling time-window scores (A, B or C scores), this will be indicated by a red traffic light symbol. It is the responsibility of the laboratory to undertake an internal investigation to establish the underlying cause and put in place corrective and preventive action. Please do not wait to receive a formal notification of performance from the Scheme Organiser or the National Quality Assurance Advisory Panel (NQAAP) before logging the non-conformity and, where necessary, acting upon the data contained in your report. A green traffic light merely reflects that your laboratory is performing as well as the state-of-the-art allows; it does not necessarily mean that your assay / laboratory performance is good enough clinically.

	Specimen	Pool	Result	Target	Specimen %bias	A score	B score	C score	A	B	C
Insulin (pmol/L)	976	N248	84	76.27	+10.1	113	-13.8	20.0	↗	↗	↗
	977	N270	970	378.09							
	978	N271	33	41.54	-20.6						
C-Peptide (pmol/L)	976	N248	183	256.5	-28.7	133	-21.5	8.7	↔	↔	↔
	977	N270	600	621.3	-3.4						
	978	N271	339	375.4	-9.7						
Gastrin (mU/L)	976	G178	87	70.5	+23.4	273	+7.2	45.7	↗	↔	↔
	977	G177	53	44.5	+19.0						
	978	G176	27	17.6	+53.0						
IGF-I (nmol/L)	976	F217	13.1	13.70	-4.4	75	-8.0	6.1	↗	↔	↔
	977	F215	13.7	14.50	-5.5						
	978	F216	21.5	22.28	-3.5						
IGFBP3 (mg/L)	976	F217	4.1	3.580	+14.5	64	-0.7	12.0	↘	↗	↘
	977	F215	4.2	3.710	+13.2						
	978	F216	4.8	4.385	+9.5						

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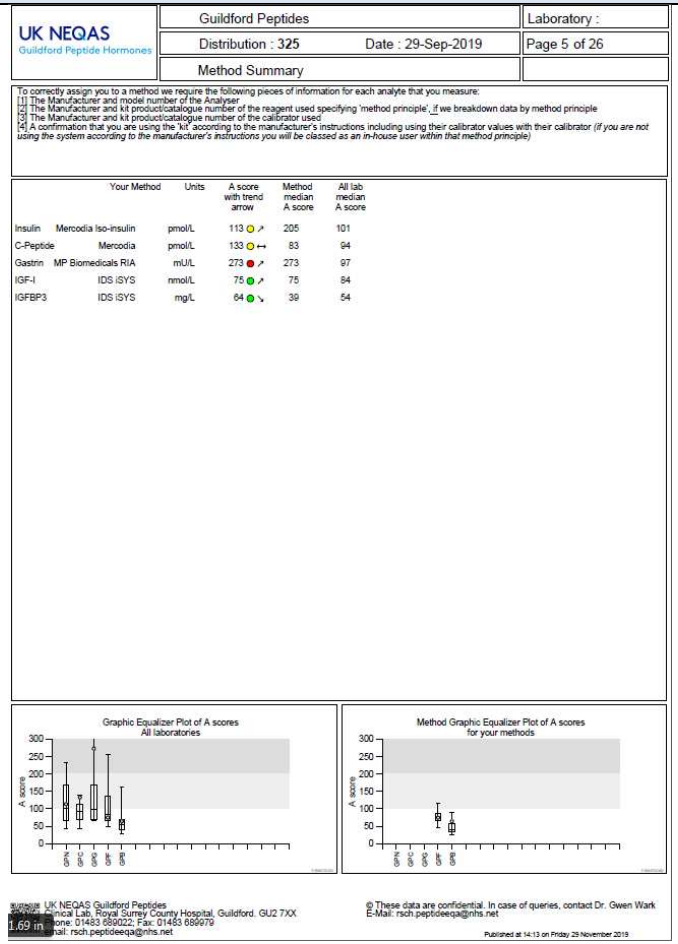
This is a summary of this distribution. It includes all results returned for the distribution, the target results, pool and sample identifiers, specimen biases and your current performance scores. The traffic light system makes it easy to see whether you are performing acceptably or not.

Method Summary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Distribution : 325 Date : 29-Sep-2019 | Page 5 of 26

Method Summary

To correctly assign you to a method we require the following pieces of information for each analyte that you measure:
[1] The Manufacturer and model number of the Analyser
[2] The Manufacturer and kit product/catalogue number of the reagent used specifying 'method principle', if we breakdown data by method principle
[3] The Manufacturer and kit product/catalogue number of the calibrator used
[4] A confirmation that you are using the 'kit' according to the manufacturer's instructions including using their calibrator values with their calibrator *(if you are not using the system according to the manufacturer's instructions you will be classed as an in-house user within that method principle)*

	Your Method	Units	A score with trend arrow	Method median A score	All lab median A score
Insulin	Mercodia Iso-insulin	pmol/L	113 ↗	205	101
C-Peptide	Mercodia	pmol/L	133 ↔	83	94
Gastrin	MP Biomedicals RIA	mU/L	273 ↗	273	97
IGF-I	IDS iSYS	nmol/L	75 ↗	75	84
IGFBP3	IDS iSYS	mg/L	64 ↘	39	54

Graphic Equalizer Plot of A scores
All laboratories

Method Graphic Equalizer Plot of A scores
for your methods

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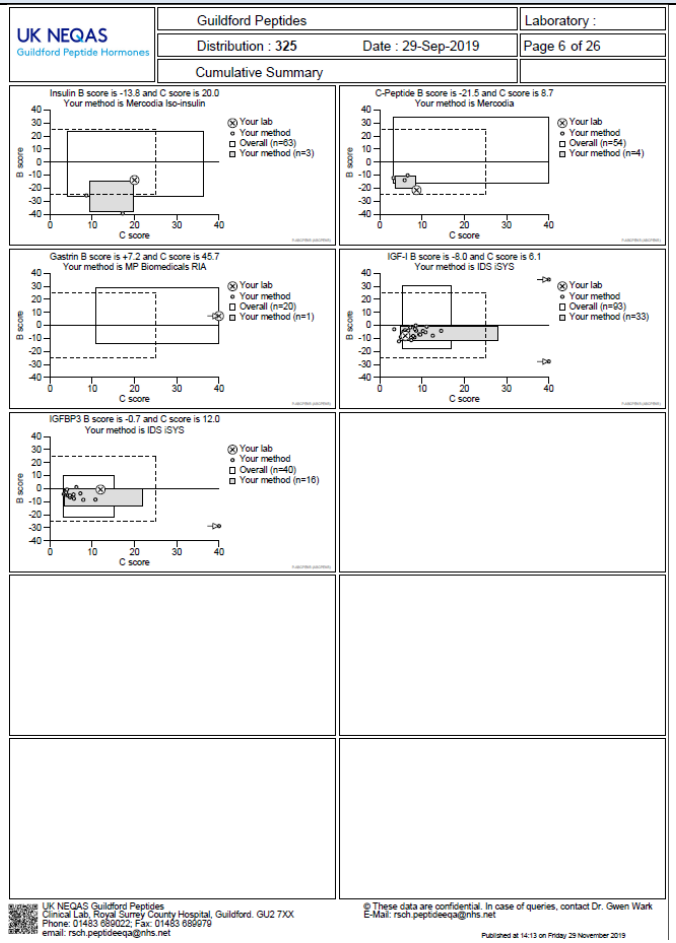
The Method Summary page allows participants to see how their A scores compare against other users of their method and how their method compares against others.

Cumulative Summary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Cumulative Summary

Insulin B score is -13.8 and C score is 20.0
Your method is Mercodia Iso-insulin

C-Peptide B score is -21.5 and C score is 8.7
Your method is Mercodia

Gastrin B score is +7.2 and C score is 45.7
Your method is MP Biomedicals RIA

IGF-I B score is -8.0 and C score is 6.1
Your method is IDS iSYS

IGFBP3 B score is -0.7 and C score is 12.0
Your method is IDS iSYS

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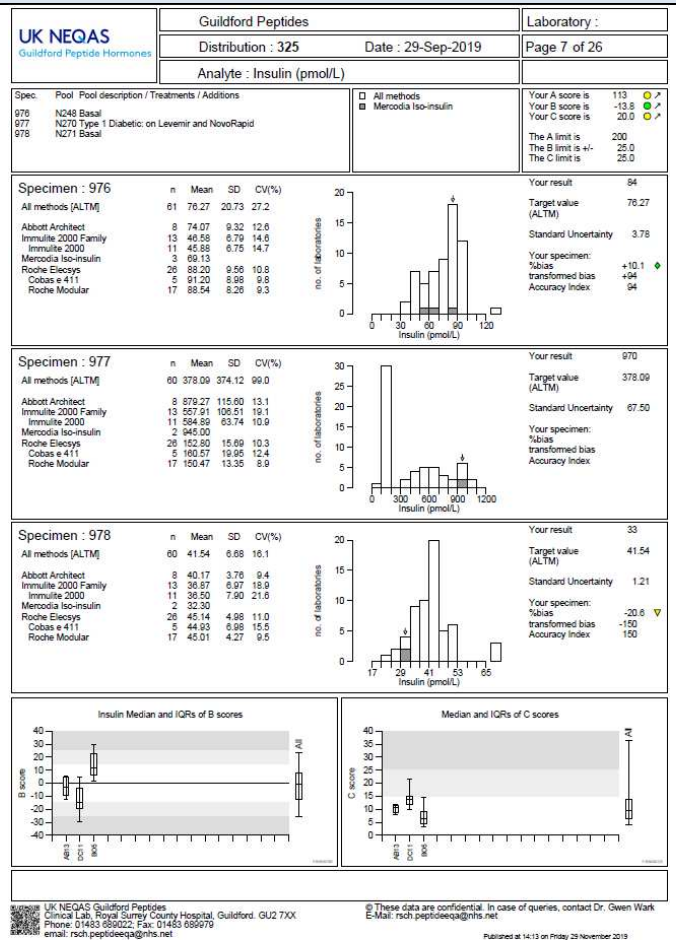
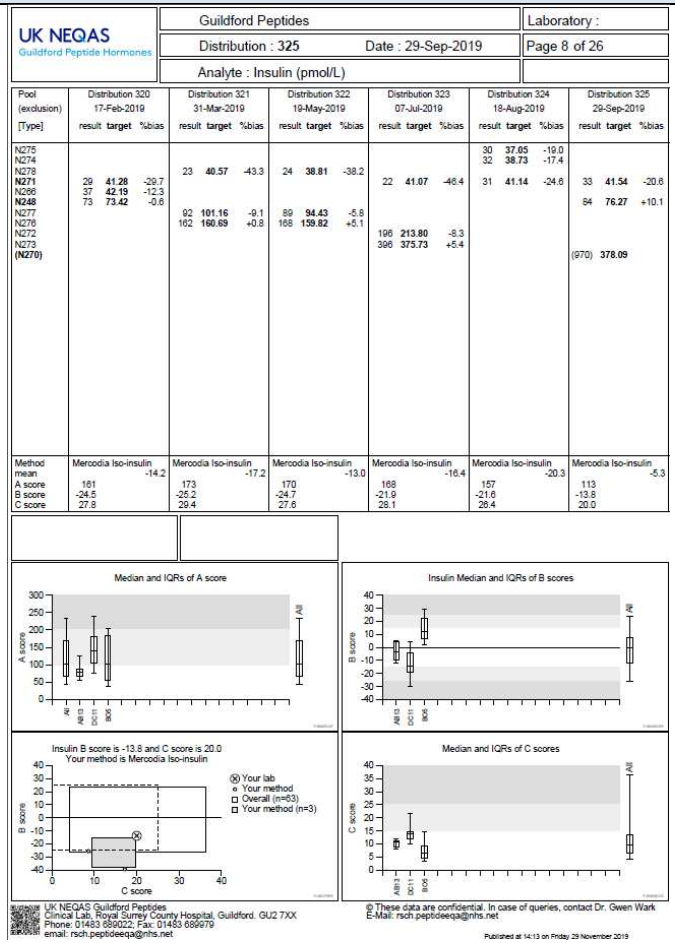
This page shows larger versions of the penalty box plots shown on the performance summary page for each analyte.

Example Analyte (Insulin) Detailed Report- Page 1



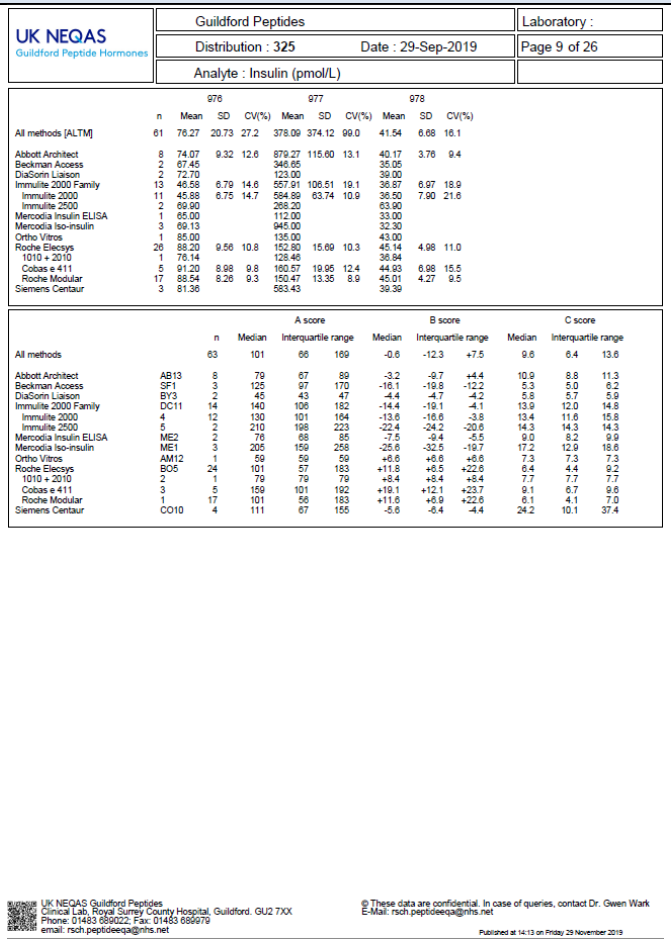
This is the first Analyte page for insulin. This is replicated for each analyte the participant is registered for. Here the user can view more detailed breakdowns of data from different methods, histograms showing the distribution of results as well as more information such as the SD of results and the uncertainty of measurement. This report shows an educational sample (977). This is for a patient on treatment for type 1 Diabetes. The sample was issued to ensure that participants understand how their instrumentation is affected by clinical therapy. It was removed from the cumulative performance scoring.

Example Analyte (Insulin) Detailed Report- Page 2



This is the second Analyte page for insulin. This is replicated for each analyte the participant is registered for. This page shows the participant results, targets, and biases of all the samples which make up the ABC scores. It also shows several graphs useful in troubleshooting an assay.

Example Analyte (Insulin) Detailed Report- Page 3



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Distribution : 325 Date : 29-Sep-2019 | Page 9 of 26
Analyte : Insulin (pmol/L)

	n	976 Mean	SD	CV(%)	n	977 Mean	SD	CV(%)	n	978 Mean	SD	CV(%)
All methods [ALTM]	61	76.27	20.73	27.2	378.09	374.12	99.0		41.54	6.68	16.1
Abbott Architect	8	74.07	9.32	12.6	879.27	115.60	13.1		40.17	3.76	9.4
Beckman Acoess	2	67.45			346.65				35.05		
DiaSorin Liaison	2	72.70			123.00				39.00		
Immulite 2000 Family	13	46.58	6.79	14.6	557.91	106.51	19.1		36.87	6.97	18.9
Immulite 2000	11	45.88	6.75	14.7	584.89	63.74	10.9		36.50	7.90	21.6
Immulite 2500	2	69.90			268.20				63.90		
Mercodia Insulin ELISA	1	65.00			112.00				33.00		
Mercodia Iso-insulin	3	69.13			945.00				32.30		
Ortho Vitros	1	85.00			135.00				43.00		
Roche Elecsys	26	88.20	9.56	10.8	152.80	15.69	10.3		45.14	4.98	11.0
1010 + 2010	1	76.14			128.46				38.94		
Cobas e 411	5	91.20	8.98	9.8	160.57	19.95	12.4		44.93	6.98	15.5
Roche Modular	17	88.54	8.26	9.3	150.47	13.35	8.9		45.01	4.27	9.5
Siemens Centaur	3	81.36			583.43				39.39		

		n	A score Median	A score Interquartile range		B score Median	B score Interquartile range		C score Median	C score Interquartile range	
All methods		63	101	66	169	-0.6	-12.3	+7.5	9.6	6.4	13.6
Abbott Architect	AB13	8	79	67	89	-3.2	-9.7	+4.4	10.9	8.8	11.3
Beckman Acoess	SF1	3	125	97	170	-16.1	-19.8	-12.2	5.3	5.0	6.2
DiaSorin Liaison	BY3	2	45	43	47	-4.4	-4.7	-4.2	5.8	5.7	5.9
Immulite 2000 Family	DC11	14	140	106	182	-14.4	-19.1	-4.1	13.9	12.0	14.8
Immulite 2000	4	12	130	101	164	-13.6	-16.6	-3.8	13.4	11.6	15.8
Immulite 2500	5	2	210	198	223	-22.4	-24.2	-20.6	14.3	14.3	14.3
Mercodia Insulin ELISA	ME2	2	76	68	85	-7.5	-9.4	-5.5	9.0	8.2	9.9
Mercodia Iso-insulin	ME1	3	205	159	258	-25.6	-32.5	-19.7	17.2	12.9	18.6
Ortho Vitros	AM12	1	59	59	59	+6.6	+6.6	+6.6	7.3	7.3	7.3
Roche Elecsys	BO5	24	101	57	183	+11.8	+6.5	+22.6	6.4	4.4	9.2
1010 + 2010	2	1	79	79	79	+8.4	+8.4	+8.4	7.7	7.7	7.7
Cobas e 411	3	5	159	101	192	+19.1	+12.1	+23.7	9.1	6.7	9.6
Roche Modular	1	17	101	56	183	+11.6	+8.9	+22.6	6.1	4.1	7.0
Siemens Centaur	CO10	4	111	67	155	-5.6	-6.4	-4.4	24.2	10.1	37.4

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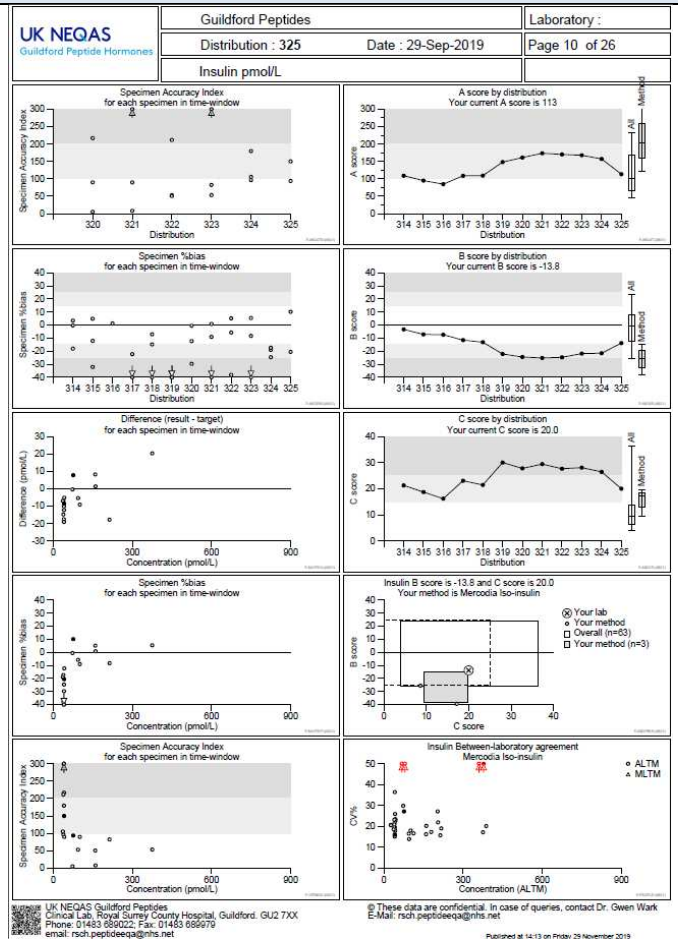
This is the third Analyte page for insulin. This is replicated for each analyte the participant is registered for. It further breaks down the different methods and provides you with detailed information about how the methods compare. This is particularly useful when troubleshooting assays or when looking to purchase new equipment.

Example Analyte (Insulin) Detailed Report- Page 4



This is the fourth Analyte page for insulin. This is replicated for each analyte the participant is registered for. The final page shows a number of graphs including how scores have changed over time and how your lab and method compare against other participants. This is particularly useful when troubleshooting assays.

Appendix A: Limits of Acceptable Performance

A Score	
<100	Better than average performance (Green)
101 - 200	Worse than average performance but within acceptable performance limits (Amber)
>200	Worse than average performance and outside acceptable performance limits (Red)

B Score	
<±25%	Acceptable performance
>±25%	Unacceptable performance

C Score	
<25%	Acceptable performance
>25%	Unacceptable performance

Participants will be defined as poor performers under the following circumstances:

- Having an average B Score out- with the stated limits
- Having an average C Score out-with the stated limits

- Failure to return for 1 or more distributions in a 6 distribution period unless valid reason for non-return has been communicated to the Scheme Organise
- Returning results late for 2 or more distributions in a 6 distribution period
- Having 2 or more blunders in a 6 distribution period