

# Participant's Manual

# UK NEQAS

## For Trace Elements

UK NEQAS for Trace Elements  
Surrey Research Park  
15 Frederick Sanger Road  
Guildford, Surrey  
GU2 7YD



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## 1. Schemes Provided

Scheme	Analytes
<b>Serum trace elements</b>	Aluminium, chromium, cobalt, copper, selenium, zinc.
<b>Whole blood trace elements</b>	Arsenic, cadmium, chromium, cobalt, lead, magnesium, manganese, mercury, selenium, thallium, zinc.
<b>Urine trace elements</b>	Arsenic, cadmium, chromium, cobalt, copper, iron, lead, manganese, mercury, nickel, selenium, thallium, zinc.
<b>Water and dialysis fluids</b> (For educational purposes only)	Aluminium
<b>Solid Matrix</b> (For educational purposes only)	Copper, iron.

## 2. Background and Aims

The UK NEQAS for Trace Elements external quality assessment scheme operates from Guildford, Surrey in the United Kingdom from purpose built laboratories on the Surrey Research Park. The Scheme is managed and administered by staff employed by Royal Surrey County Hospital NHS Foundation Trust. The scheme is part of Berkshire and Surrey Pathology Services (BSPS), the overarching organisation that manages the various individual pathology departments that operate across the Foundation Trusts involved in the BSPS partnership: Ashford and St Peter's Hospital (ASPH), Frimley Health (FH), Royal Berkshire Hospital (RBH) and Royal Surrey County Hospital (RSCH).

The legal entity for the scheme is Frimley Health NHS Foundation Trust.

Specimens are sent from Guildford to UK and overseas participants by mail or courier service. Results are returned by logging onto a web-based system using a unique username and password, and the reports are available to download from the same website. Communication with the scheme via email (rsc-tr.Guildford-EQA@nhs.net) is the preferred option.

The aims of UK NEQAS for Trace Elements are consistent with the intentions of UK NEQAS, 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
- stimulate the overall improvement in performance among all participating laboratories

### 3. Address and Communication

UK NEQAS for Trace Elements  
Surrey Research Park  
15 Frederick Sanger Road  
Guildford  
Surrey  
GU2 7YD

Telephone: + 44 (0) 1483 689022  
Fax: + 44 (0) 1483 689979  
Email: [rsc-tr.guildford-eqa@nhs.net](mailto:rsc-tr.guildford-eqa@nhs.net)

Opening Hours: **9:00 – 17:00** (UK time) with the exception of the bank and public holidays

An information web site for the scheme exists at <http://surreyegas.org.uk/>

The website for reporting a result is [www.birminghamquality.org.uk](http://www.birminghamquality.org.uk)

A website for the UK NEQAS organisation and which also gives specific information for certain UK NEQAS Centres and Schemes, including the scheme is at [www.uknegas.org.uk](http://www.uknegas.org.uk)

Information about the SAS Trace Elements Laboratory at Guildford may be found at [http://www.nhspathology.fph.nhs.uk/Core-Service/Test-Directory/Biochemistry/Trace\\_Elements.aspx](http://www.nhspathology.fph.nhs.uk/Core-Service/Test-Directory/Biochemistry/Trace_Elements.aspx)

**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.

### 4. Staffing

Dr Andrew Taylor Scheme Director	Tel. - 01483 689977 Email: andrewtaylor4@nhs.net
Dr Chris Harrington Scheme Manager	Tel. - 01483 689977 Email: chris.harrington1@nhs.net
Miss Sarah-Jane Bainbridge EQA Quality Manager	Tel. - 01483 57112 Ext. 4479 Email: SBainbridge1@nhs.net
Mr Jonathan Dart Medical Technical Officer	Tel. - 01483 689022 Email: jonathan.dart@nhs.net
Mr Geoff Carpenter SAS laboratory contact	Tel. - 01483 689978 Email: g.carpenter@nhs.net

### 5. Accreditation and Recognition

The schemes were formally recognised by the Joint Working Group for Quality Assurance according to the criteria developed for EQA providers in 1993. These have been superseded by the EQA accreditation standards of Clinical Pathology Accreditation (UK) Ltd. The schemes were fully accredited by CPA in 2000 and have been successfully re-assessed thereafter. In 2015 the **blood, serum and urine programme** was assessed and obtained ISO 17043:2010 (General requirements for proficiency testing) accreditation **although the solid matrix and aluminium in water programmes are for educational purposes only and are not accredited to ISO 17043:2010.**

## 6. Participation

### 6.1 Eligibility

The UK NEQAS for Trace Elements external quality assessment scheme is designed principally for laboratories serving clinicians and patients. Initially established for UK hospital laboratories there are now many non-UK health care participants, research laboratories and other establishments that take part in the scheme. All UK clinical service laboratories who are participants in the scheme must agree to current Joint Working Group (JWG) Conditions of Participation (see Appendix 1). By returning a completed registration form participants are deemed by the scheme management to have agreed to these conditions of participation.

Participants should note that data generated by the scheme are the copyright of UK NEQAS for Trace Elements. Reports may only be distributed, published or used for publicity and promotion with the written consent of the Scheme Organizer. Permission for scientific use or reports and scheme data will not be unreasonably withheld but please ask in advance.

### 6.2 Enrolment

Intending participants should contact the Scheme Organiser for enrolment documents which include:

- Registration form/price list.
- Method questionnaire.
- A schedule of specimen dispatch dates.
- Packing insert detailing sample handling requirements.

Although the main **blood, serum and urine programmes** operates a succession of six-monthly cycles which commence in April and October each year, it is possible for participation to begin at the first distribution after receipt of a completed registration form. Charges will be applied on a pro-rata basis.

### 6.3 Participant code numbers

Each participant is assigned a unique code number which is common to all UK NEQAS schemes.

**Please quote your laboratory code number in all communications with the Scheme.**

### 6.4 Confidentiality

The fact of participation, raw data and performance scores are confidential between the individual laboratory and the Scheme staff. For UK laboratories providing services to NHS organisations, performance scores (and some relevant raw data) may be shared with the Advisory Panel under defined circumstances (see Appendix 1) as part of the 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.*

## 6.5 Charges

The scale of charges is published annually and is available on request. The charging period is 1st April to 31st March and participation for part of a year will be charged pro-rata. All financial matters are managed by Frimley Health NHS Foundation Trust who arranges invoicing for the services provided. The financial details for payment are as follows:

For all laboratories:

**Bank account name** - Frimley Health NHS Foundation Trust

**Bank name** - Lloyds TSB, 19-23 Obelist Way, Camberley, Surrey, GU16 3SE

**Sort code** - 30-91-53

**Account No** – 01198646

Extra information for overseas laboratories:

**Bank ID** - Identifier Code Loyd GB21141 (*the words 'Identifier Code' does need to be quoted and spelling 'Loyd' with one 'L' is correct*)

**IBAN No** - GB96LOYD30915301198646

**Swift Code** - LOYD GB2L

## 7. Specimens

### 7.1 Types

Specimens are prepared using serum, whole blood, urine, dialysis fluids and drinking water as the base material. The solid matrix specimens are prepared using lyophilised, powdered muscle, tissue and other materials.

### 7.2 Sources

*Serum:* New born bovine calf serum is obtained from Selborne Biological Services.

*Blood:* Sterile equine blood, is collected and stored with EDTA as anticoagulant and is obtained from TCS Biosciences Ltd.

*Urine:* Human urine from anonymised surplus pathological 24hr urine collections.

*Dialysis fluid and Water:* Dialysis fluid concentrate, Renalyte, is purchased from Macarthays Medical Ltd., Romford, UK.

*Solid matrix:* European Reference Material, lyophilised and powdered muscle, tissue and other materials are obtained from IRMM, Geel, Belgium.

### 7.3 Preparation and treatment

*Serum:* New-born calf serum is chelexed for 24hrs then centrifuged for preparation of six serum pools. Five are supplemented with Al, Cr, Co, Cu, Se and Zn. The serum is transferred to volumetric flasks which are mixed and dispensed into labelled tubes.

*Blood:* Equine blood is transferred to volumetric flasks for supplementation with As, Cd, Cr, Co, Pb, Mg, Mn, Hg, Se, Tl and Zn. The blood samples are mixed and dispensed into labelled tubes.

*Urine:* Human urine is acidified with concentrated nitric acid to a final volume of 1% and then kept at approximately **-20 °C** for at least 24 hours. After thawing to room temperature the urine is

filtered to remove precipitates, placed into volumetric flasks and the concentrations of As, Cd, Cr, Co, Cu, Fe, Pb, Mn, Hg, Ni, Se, Tl and Zn augmented as for elements in serum or blood. The samples are mixed and dispensed into labelled tubes.

*Dialysis fluid and water:* Dialysis concentrate 28.5 ml, is pipetted into a 1 l volumetric flask containing aluminium-free water. Nitric acid, 10 ml, and a solution of Al to increase the final concentration by a pre-determined amount, are added, made to volume with deionised water and thoroughly mixed. Water specimens are similarly prepared except for omission of the dialysis concentrate.

*Solid Matrix:* Lyophilised sample is dried to constant weight before weighing aliquots of approximately 0.015 g into 1.5 mL microcentrifuge tubes. Samples may be supplemented with Cu and Fe.

Serum, blood and urine specimens are subjected to gamma-irradiation (25-38 kilogray) to destroy any bacterial contamination that may have occurred during preparation. These specimens are stored at +4°C until dispatched.

The homogeneity and stability of sample batches have been demonstrated for representative batches of samples and is checked on an ongoing basis.

#### 7.4 Safety precautions

The procedures employed for the preparation and treatment of specimens should ensure that there are no risks associated with their use. **However, as for all clinical material, EQA samples should be handled with the same precautions as are normally adopted in the handling of patient specimens. Appropriate precautions should be used during receipt, storage, preparation for analysis and their disposal.**

## 8. Operation

### 8.1 Distribution cycle

For each annual cycle of the blood, serum and urine programme, a total of twelve pools are prepared as described above, resulting in a total of six pools for each of the 6 monthly dispatches. Two specimens are analysed every month and each pool is sent for analysis on two different occasions. Thus, the cycle provides 24 specimens with duplicate measurements on the 12 pools. The dialysis fluid and water specimens are prepared fresh each month and do not follow a fixed term cycle. The solid matrix samples are dispatched in a quarterly cycle providing 3 specimens for analysis in each distribution.

### 8.2 Mailing, storage and testing

Specimens for the blood, serum and urine are despatched as liquid samples and sent to the participants by post or courier. Laboratories are requested to analyse samples for the first month as soon as possible after receipt and to store the other specimens until the appropriate time, at a temperature of at least -20 °C. Once thawed the specimens should reach room temperature and be thoroughly mixed prior to analysis (this is particularly important for the whole blood samples). The dialysis fluid and water specimens are sent monthly, immediately after preparation and should be analysed as soon as possible after receipt. Precaution should be taken on opening against contamination of the samples by dust containing Al. The solid matrix samples are

dispatched as lyophilised powdered samples and are packaged in jiffy bags. The specimens should be stored at  $18^{\circ}\text{C} \pm 5^{\circ}\text{C}$ .

Special arrangement may be made for overseas participants if delivery delays or other problems have been experienced. A schedule of specimen despatch dates is provided each year upon registration. Participants should allow 7 days for delivery and if they have not been received by the due date the organizers should be informed (section 3).

The proficiency testing specimens should be tested in the same manner as the majority of routine samples that the participant laboratory receives for analysis. The specimens should be defrosted, allowed to reach room temperature and then thoroughly mixed before aliquoting the sample out for testing. The participant should use the same instrumentation and calibration methods that are used for the patient samples that they test.

### 8.3 Results documents

For the monthly Scheme participants should use their own form for recording their results, in the same way that they do for normal patient samples eg units and decimal places the same.

For the aluminium, and solid matrix schemes, result forms carrying the participation code number and showing the date by which results must be returned are sent with the specimens. Participants can use their own forms for sending in results but should make sure that there is no ambiguity concerning the units of concentration.

### 8.4 Reporting procedures

For the blood, urine and serum scheme, results should be reported using the password-protected website facility: UKNEQAS ([www.birminghamquality.org.uk](http://www.birminghamquality.org.uk)). Where this is not possible results may be returned by post, fax or email to the Scheme office. Please make sure that results are written clearly and that decimal points are shown as there can be loss of clarity when sent by fax. Results received after the 'return by --' date will be included provided the reporting software has not yet been initiated. Other late results will be entered so that they contribute to the average Z-scoring.

The on-screen report shows the date and time when the report was authorised. Reports issued within 5 working days of the reporting deadline and up to 1 month following the reporting deadline are interim reports. A final report will be issued on the same day as the next month's interim report. For this reason amendments to results will only be accepted up to one month after close of the distribution. Amendments will not be accepted following receipt of the final report (see section 11.1 Blunders and Amendments to results).

For the aluminium, and solid matrix scheme samples, results should be returned to the office by the closing date of the distribution.

Null returns, ie a positive statement that no results are available, should be made when there are situations such as; no patients' samples available to analyse, instrument or staffing problems.



## 9. Data Processing

### 9.1 Assigned concentrations

In most situations the robust consensus mean and standard deviation are used to represent the assigned concentration. These data have been demonstrated to represent a close approximation to the true value.

### 9.2 Validity of targets

Targets are checked at intervals by comparison with the recoveries of added analytes. Further work is undertaken from time to time with measurements of Certified Reference Materials, where traceability to a primary standard is possible, and by examination of results from reference laboratories.

### 9.3 Surveillance

As each distribution is processed, Organisers carefully check the resulting data. If you suspect that we have made an error, let us know immediately. It is important that we can act speedily and improve the way in which we manage the organisation.

## 10. Reports

### 10.1 Overview

Results reported by participants are downloaded from the website and entered into a computer programme for calculation of the robust mean and standard deviation, median and coefficient of variation for each of the matrix/analyte/specimen combinations. Unique monthly reports are prepared for each participant which show these values and also gives the participants own results and histogram displays of the distributions of results (Appendix 2). A performance score (z-score) is produced to accompany the report (see below). Participants can access a copy of their report via the website using their own password within 5 working days of the result submission deadline. Where this is not possible, copies can be printed at the Scheme Office and posted or emailed as pdf files to participants. The on-screen report shows the date and time when the report was authorised. Reports issued within 5 working days of the reporting deadline and up to 1 month following the reporting deadline are interim reports. A final report will be issued on the same day as the next month's interim report. For this reason amendments to results will only be accepted up to one month after close of the distribution. Amendments will not be accepted following receipt of the final report (see section 11.1 Blunders and Amendments to results).

### 10.2 Performance scores: Z-scoring

Measurements of performance are based on deviations of results from target values. These deviations are used to calculate a Z-score.

As external quality assessment has developed, various organisations have produced documents that summarise best practice. Those from authoritative international bodies include:

- ISO 17043 (Conformity assessment - General requirements for proficiency testing).
- ISO 13528 (Statistical methods for use in proficiency testing by interlaboratory comparisons).
- IUPAC (The international harmonized protocol for the proficiency testing of analytical chemistry laboratories, Pure Appl. Chem. 2006; 78: 145–196, 2006).

All these documents recommend that assessment of performance should be based upon calculation of a Z-score (or a derivative which takes uncertainty into consideration). Z-scores are now widely used in EQA schemes around the world including other sectors in the UK.

The Z-score is calculated as

$$\frac{x-X}{SD_{PT}}$$

where  $x$  = laboratory result,

$X$  = target value and

$SD_{PT}$  = standard deviation for proficiency testing (also represented as  $\sigma$ )

The 'standard deviation for proficiency testing' is set by the scheme organiser but should ideally be a value that will allow the score to demonstrate whether or not the performance is fit for the purpose for which the assay is being used. It is recommended that this value be set so that a Z-score of up to  $\pm 2$  indicates acceptable performance and a score of more than  $\pm 3$  indicates unsatisfactory performance.

For the Trace Elements EQAS we have used quality specifications based on biological variation for the 'standard deviation for proficiency testing'. The determination of these quality specifications is described in Arnaud et al. Clinical Chemistry 2008; 54: 1892-9. For assays where there is insufficient data to prepare specifications in this way we have produced values that are related to performance within the scheme during recent years. All have been approved by the scheme steering group.

The quality specifications and their corresponding  $SD_{PT}$  are shown in the table below. These are presented as either a percentage of the target value or a fixed value depending on the concentration of the target value, and the one used is whatever is the greater. This allows for the increase in imprecision at low concentrations and conforms to a 'funnel' shape as seen in the accompanying figure. The concentration at which the change from percentage to fixed value takes place (inflection point) is given by;

$$\text{Inflection point} = (\text{fixed concentration}/\text{fixed percentage}) * 100$$

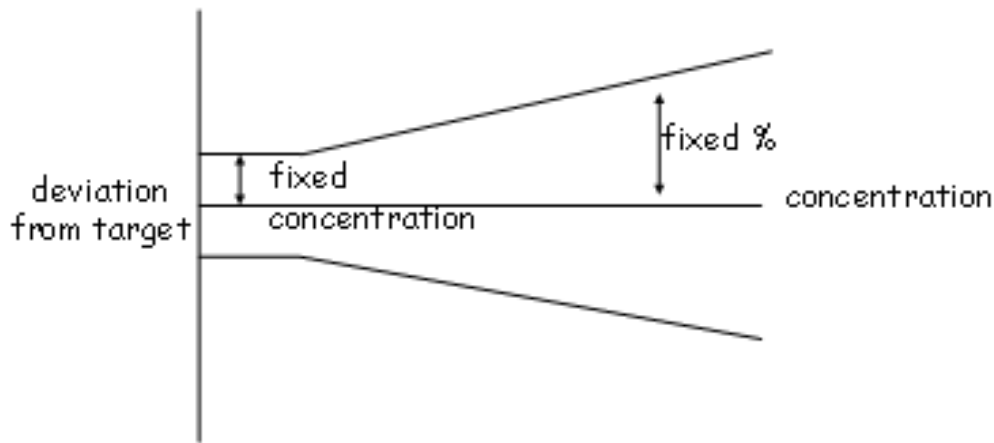
Matrix-Analyte	Scheme Units	Quality specification		SD <sub>PT</sub>		Inflection Point
		%	fixed	%	fixed	
<b>Serum</b>						
Aluminium	µmol/L	20	0.19	10	0.095	0.95
Chromium	nmol/L	20	40	10	20	200
Cobalt	nmol/L	15	25	7.5	12.5	167
Copper	µmol/L	12	0.84	6	0.42	7
Selenium	µmol/L	12	0.072	6	0.036	0.60
Zinc	µmol/L	15	1.2	7.5	0.6	8
<b>Blood</b>						
Arsenic	nmol/L	12.5	25	6.25	12.5	200
Cadmium	nmol/L	10	3	5	1.5	30
Chromium	nmol/L	20	40	10	20	200
Cobalt	nmol/L	20	25	10	12.5	125
Lead	µmol/L	10	0.145	5	0.0725	1.50
Magnesium	mmol/L	7.2	0.01	3.6	0.005	0.14
Manganese	nmol/L	15	75	7.5	37.5	500
Mercury	nmol/L	15	10	7.5	5	67
Selenium	µmol/L	12	0.072	6	0.036	0.60
Thallium	nmol/L	25	0.05	12.5	0.025	0.20
Zinc	µmol/L	10	1.5	5	0.75	15
<b>Urine</b>						
Arsenic	nmol/L	12.5	25	6.25	12.5	200
Cadmium	nmol/L	25	1	12.5	0.5	4
Chromium	nmol/L	20	60	10	30	300
Cobalt	nmol/L	15	25	7.5	12.5	167
Copper	µmol/L	20	0.25	10	0.125	1.25
Iron	µmol/L	15	4	7.5	2	27
Lead	nmol/L	5	12.5	2.5	6.25	250
Manganese	nmol/L	25	10	12.5	5	40
Mercury	nmol/L	25	23	12.5	11.5	92
Nickel	nmol/L	7.5	25	3.75	12.5	333
Selenium	µmol/L	25	0.3	12.5	0.15	1.20
Thallium	nmol/L	5	2.5	2.5	1.25	50
Zinc	µmol/L	20	1	10	0.5	5

NB the quality specifications for urine cadmium and mercury, and blood cadmium and mercury where updated by the Specialist Advisory Group for Trace Elements at a meeting on 19<sup>th</sup> April 2017.

**Examples:**

A blood sample has a lead concentration of 2.0 µmol/L. The  $SD_{PT}$  could be 0.1 µmol/L ( $\pm 5\%$ ) or 0.0725 µmol/L (fixed value). As 0.1 is the greater value this would be used. For a laboratory reporting a result of 2.2 µmol/L the calculation would be  $(2.2-2.0)/0.1$ , and the z-score is +2.00.

A serum samples has a zinc concentration of 5.0 µmol/L. The  $SD_{PT}$  could be 0.375 µmol/L ( $\pm 7.5\%$ ) or 0.6 µmol/L (fixed value). As 0.6 is the greater value this would be used. For a laboratory reporting a result of 5.5 µmol/L the calculation would be  $(5.5-5.0)/0.6$ , and the z-score is +0.83.



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**10.3 Monthly reports**

In addition to the descriptive statistics and histogram the monthly report shows a monthly z-score and the z-score performance over the previous 12 months of the scheme. The reports can be downloaded from the UKNEQAS website [www.birminghamquality.org.uk](http://www.birminghamquality.org.uk).

**10.4 Collusion**

It is a requirement of participation that results may not be shared among participants before reports have been issued (ISO 17043; 4.4.1.3j). In the event of collusion being suspected the laboratory will be asked to provide evidence that their results are genuine. If confirmed and there is no adequate explanation, the head of department and/or employing authority may be informed

## 11. Performance

### 11.1 Blunders and amendments to results

These are defined as errors, which may or may not be detected as outliers and a record is kept by the scheme of blunders that occur. Participants are allowed one blunder per scheme year, depending on the circumstances and risk relating to the any further blunders, they maybe 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. The policy on blunder correction is:

1. Amendments prior to the reporting deadline. Amended copies of already entered results should be clearly marked "Amended Copy" with the change unambiguously highlighted and returned to us by either fax or email.
2. Amendments up to 2 working days after the reporting deadline. Please telephone, fax or email to explain the problem. Results can usually be amended and an updated report produced. These should be reported in writing with an explanation for 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. A copy or screen print of the experiment with evidence of the original results and analysis date will be requested. However, the fact that incorrect results were reported will be recorded as a blunder.
3. Amendments up to 1 month after receipt of reports. These should be reported in writing with an explanation for 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. A copy or screen print of the experiment with evidence of the original results and analysis date will be requested. However, the fact that incorrect results were reported will be recorded as a blunder.
4. After 1 month following the reporting deadline a final report will be issued. Once a final report has been issued amendments to results will not be accepted. Only in exceptional circumstances will amendments be considered, however these will be made under discretion of the Scheme Manager or Director.
5. Amended reports will be given a unique identification with reference to the original report and include a statement concerning the reason for the amendment.

## 11.2 Performance criteria

A laboratories performance is assessed using the z- scores shown on the monthly reports and the number of participant blunders. More than one blunder in a scheme year may be consider poor performance. Scores of  $> \pm 2$  indicate action is required to bring the method under control

## 11.3 Performance surveillance, the Advisory Panel and persistent poor performance

The poor performance criteria is as follows:

- 3 or more z-scores greater than 2 from the last 6 samples (ie covering a time span of 3 months) or,
- 2 or more z-scores greater than 3 from the last 4 samples (ie covering a time span of 2 months).
- More than one blunder per scheme year. The nature of all the blunders after the first has occurred will be assessed by the Scheme Manager and Scheme Director to determine if it should be considered poor performance.

The organisers will make informal contact with any UK NHS participant so identified and offer to assist in any work taken to rectify the problem. If performance fails to improve the organisers will notify the Chairman of the National Quality Assurance Advisory Panel for Clinical Chemistry who will follow up the situation as described in Appendix 1.

## 12. Comments, Complaints and Appeals

The on-line results documents include 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. The organisers also solicit comments when sending the annual registration forms and on various other occasions. The following criteria have been approved by the Scheme Steering Committee and the Advisory Panel (for memberships of these groups see our website at <http://surreyeqas.org.uk/>).

Complaints about any aspect of the scheme, whether scientific or operational are normally dealt with by the Scheme Manager or Director according to a written Complaints and Appeals Procedure. In the event of problems relating to day to day operational matters, please have at hand your laboratory number, the distribution date and specimen numbers. We will endeavour to rectify problems as soon as possible.

Participants may prefer to address comments or complaints, including an appeal against assessment of performance, to any member of the Scheme Steering Committee (the UK NEQAS Specialist Advisory Group for Trace Elements), the Steering Committee for Clinical Chemistry or the National Quality Assurance Advisory Panel for Chemical Pathology. Our website at <http://surreyeqas.org.uk/> gives the current memberships of these Committees.

The Scheme Manager and/or Director shall follow up on the initial response with a thorough investigation of all aspects of the problem. He or she is ultimately responsible for ensuring that appropriate corrective action has been taken.

### 13. Sub-contracted 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.

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## **Appendix 1: Joint Working Group for Quality Assurance: Conditions of EQA Scheme Participation**

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 CPA (UK) Ltd.

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 Director and should be reflected in the EQA schemes with which the laboratory is registered.
5. Samples, reports and routine correspondence may be addressed to a named deputy, but correspondence from Organisers and NQAAPs concerning persistent poor performance (red – see below) will be sent 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 Directors 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 Director 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 Director 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 2 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 resume of remedial action taken or proposed. The identity of a persistently poor 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/regulatory bodies such as CPA (UK) Ltd, 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 (black), 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 2a: Example of a Report, Serum Trace Elements**

	UK NEQAS for Trace Elements		Laboratory :			
	Distribution : FEB 2016		Date : 29-Feb-2016			
	Distribution Summary		Page 1 of 17			
	Specimen	Result	Target	Bias(%)	Z-score	Uncertainty
Serum Zinc (umol/L)	2015.21	11.5	10.77	+6.8	0.9	0.13
	2015.22	13.5	12.38	+9.1	1.2	0.14
Serum Copper (umol/L)	2015.21	10.6	10.67	-0.6	-0.1	0.11
	2015.22	11.4	11.25	+1.3	0.2	0.13
Serum Aluminium (umol/L)	2015.21	1.80	1.97	-8.6	-0.9	0.05
	2015.22	1.92	2.24	-14.2	-1.4	0.04
Serum Chromium (nmol/l)	2015.21	85	102.48	-17.1	-0.9	2.30
	2015.22	13	16.37	-20.6	-0.2	2.02
Serum Selenium (umol/L)	2015.21	1.25	1.33	-6.2	-1.0	0.03
	2015.22	0.65	0.76	-14.1	-2.4	0.02
Serum Cobalt (nmol/l)	2015.21	97	93.56	+3.7	0.3	1.68
	2015.22	81	76.53	+5.8	0.4	1.48
Blood Lead (umol/L)	2015.21	1.00	0.93	+7.8	1.0	0.01
	2015.22	1.20	1.15	+4.3	0.7	0.02
Blood Arsenic (nmol/l)	2015.21	93	78.01	+19.2	1.2	3.96
	2015.22	148	141.47	+4.6	0.5	2.97
Blood Manganese (nmol/l)	2015.21	275	270.8	+1.5	0.1	7.5
	2015.22	275	266.6	-4.0	-0.3	6.6
Blood Chromium (nmol/l)	2015.21	171	174.25	-1.9	-0.2	4.73
	2015.22	202	210.86	-4.2	-0.4	4.03
Blood Cobalt (nmol/l)	2015.21	149	143.00	+4.2	0.4	4.22
	2015.22	71	72.39	-1.9	-0.1	4.23
Blood Mercury (nmol/l)	2015.21	27	24.19	+11.6	1.1	1.31
	2015.22	49	44.45	+10.2	1.8	1.68
Urine Mercury (nmol/l)	2015.21	20	19.70	+1.5	0.0	1.63
	2015.22	44	44.76	-1.7	-0.1	4.17
Urine Copper (umol/L)	2015.21	1.24	1.29	-3.9	-0.4	0.02
	2015.22	1.93	1.88	+2.8	0.3	0.03
Urine Iron (umol/L)	2015.21	1	0.61	+62.7	0.2	0.06
	2015.22	26	27.02	-3.8	-0.5	0.75
Urine Arsenic (nmol/l)	2015.21	687	707.94	-3.0	-0.5	9.27
	2015.22	780	769.11	-1.2	-0.2	11.35
This is the Final Report.						
Frimley Health NHS Foundation Trust, operating UK NEQAS for Trace Elements (7496): Accredited to ISO/IEC 17043:2010						

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	UK NEQAS for Trace Elements	Laboratory :
	Distribution : FEB 2016      Date : 29-Feb-2016	Page 2 of 17
	Analyte : Serum Zinc (umol/L)	

Spec. Pool Pool description / Treatments / Additions	<input type="checkbox"/> All methods <input checked="" type="checkbox"/> Flame A.A.S.
2015.21 980	
2015.22 982	

**Specimen : 2015.21**

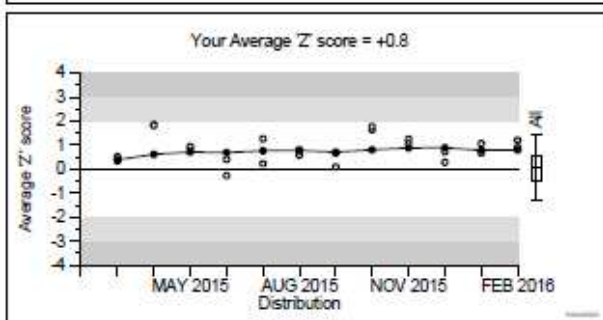
	n	Mean	SD	CV(%)
All methods (ALTM)	74	10.77	0.87	8.0
Colorimetric	2	10.31	0.13	1.3
Colorimetry	3	9.69	1.37	14.2
Colorimetry after Deproteinization	6	11.32	1.10	9.7
Electrothermal A.A.S.	1	10.43		
FAAS after Deproteinization	4	10.85	1.38	12.7
Flame A.A.S.	21	10.91	0.77	7.0
ICP-MS	15	10.48	0.76	7.2
ICP-MS (collision/reaction cell mode)	12	10.81	0.65	6.0
Z-ETAAS	3	13.47	2.68	19.9

Your result	11.5
Target value (ALTM)	10.77
Uncertainty	0.13
Your bias (%)	+6.8
Your 'Z' score	+0.9
ALTM	10.77
Median	10.70
Your method mean	10.91
Absolute range to	6.88 to 16.52

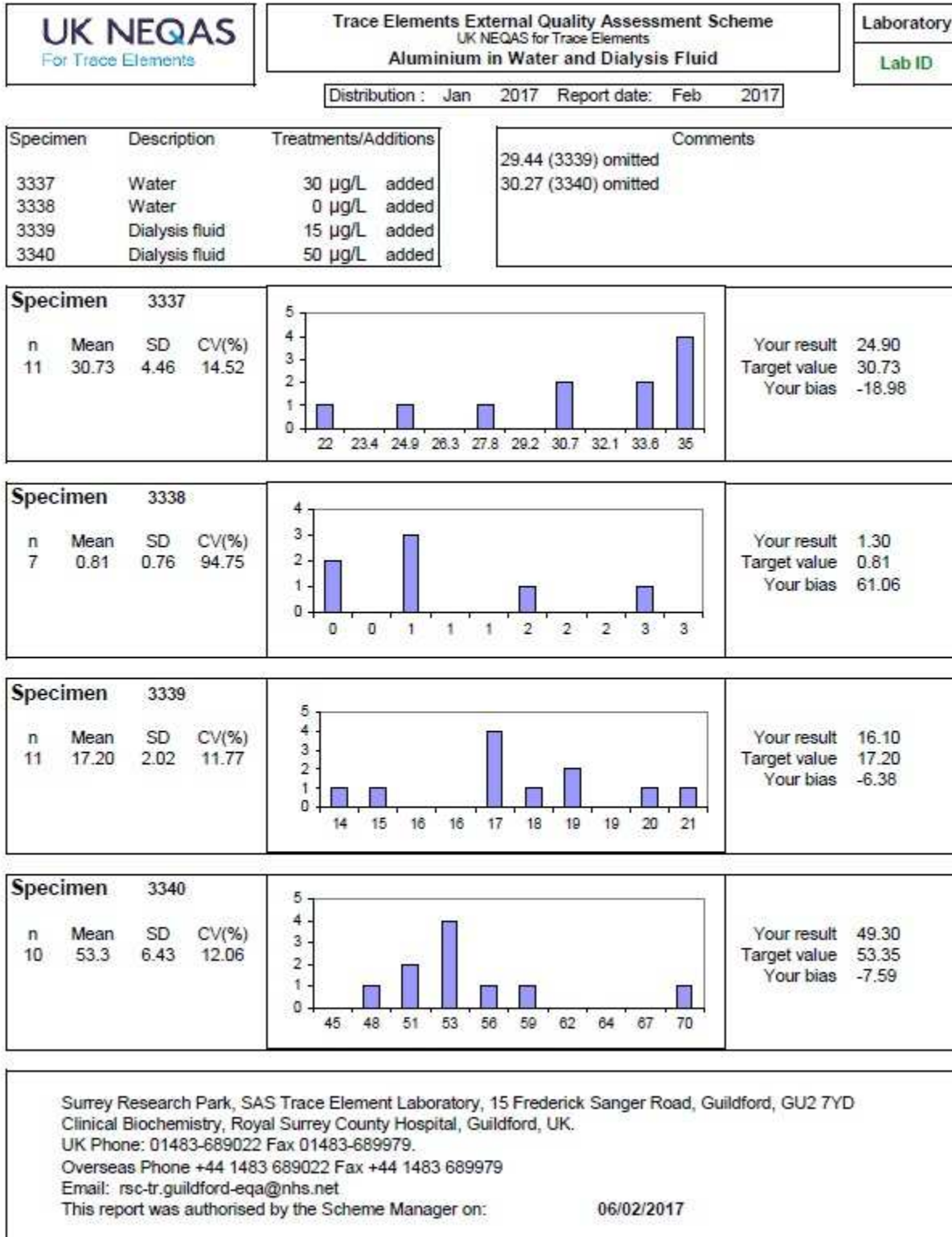
**Specimen : 2015.22**

	n	Mean	SD	CV(%)
All methods (ALTM)	74	12.38	0.93	7.5
Colorimetric	2	11.84	0.37	3.2
Colorimetry	3	10.58	0.39	3.7
Colorimetry after Deproteinization	6	12.98	0.93	7.2
Electrothermal A.A.S.	1	12.11		
FAAS after Deproteinization	4	12.38	1.64	13.3
Flame A.A.S.	21	12.56	0.88	7.0
ICP-MS	15	12.19	0.85	6.9
ICP-MS (collision/reaction cell mode)	12	12.37	0.63	5.1
Z-ETAAS	3	16.34	5.62	34.4

Your result	13.5
Target value (ALTM)	12.38
Uncertainty	0.14
Your bias (%)	+9.1
Your 'Z' score	+1.2
ALTM	12.38
Median	12.37
Your method mean	12.56
Absolute range to	10.22 to 22.79


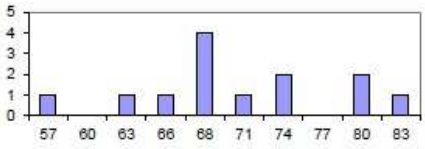
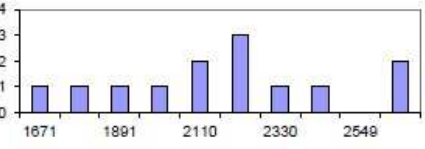
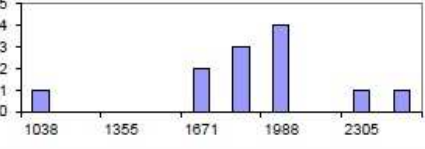


**Appendix 2b: Example of a Report, Aluminium Water / Dialysis Fluid**



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**Appendix 2c: Example of a Report, Solid Matrix**

		<b>Trace Elements External Quality Assessment Scheme</b> UK NEQAS for Trace Elements <b>Solid Matrix Scheme</b>			<b>Laboratory</b>  Lab ID	
		Distribution: Jul 2016   Report date: Sep 2016				
Specimen	Description	<b>IRON</b>		Comments		
A1	Bovine Muscle + Cu Spike	75 ug/g		Amended to include 2 further results 110.2 (A1) omitted 1232 (A2) omitted 2930 (A3) omitted		
A2	Bovine Muscle + Fe Spike	1962 ug/g				
A3	Bovine Muscle + FeCu Spike	1971 ug/L				
<b>Specimen A1 (ug/g)</b>					Your result: 65.30 Certificate value: 75.00 Your bias: -12.93	
n	ALTM	SD	CV(%)			
13	69.62	7.5	10.7			
<b>Specimen A2 (ug/g)</b>					Your result: 2303.50 Spike value: 1961.79 Your bias: 17.42	
n	ALTM	SD	CV(%)			
13	2115.45	303.6	11.9			
<b>Specimen A3 (ug/L)</b>					Your result: 1813.80 Spike value: 1971.00 Your bias: -7.98	
n	ALTM	SD	CV(%)			
12	1806.62	342.7	14.9			
Surrey Research Park, SAS Trace Element Laboratory, 15 Frederick Sanger Road, Guildford, GU2 7YD Clinical Biochemistry, Royal Surrey County Hospital, Guildford, UK. UK Phone: 01483-689022 Fax 01483-689979. Overseas Phone +44 1483 689022 Fax +44 1483 689979 Email: rsc-tr.guildford-ega@nhs.net This report was authorised by the Scheme Manager on: <span style="float: right;">06/02/2017</span>						

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