Directory and participants manual 2019-20
UK NEQAS for Microbiology
UK NEQAS for Parasitology
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Directory & Participants’ Manual

Information about the Service

Contacts for the Service

Communications

In order that your query is responded to as quickly and as efficiently as possible please provide your laboratory identification number and if relevant, the type, distribution number and specimen numbers of any specific EQA samples which you wish to discuss.

All microbiology distributions except parasitology and antibiotic assay

UK NEQAS for Microbiology
PO Box 63003
London NW9 1GH

Tel: +44 (0)20 8905 9890
Fax: +44 (0)20 8205 1488
Email: organiser@ukneqasmicro.org.uk

Antibiotic assays

UK NEQAS Birmingham Quality
Queen Elizabeth Medical Centre
PO Box 3909 Birmingham B15 2UE.
Tel: +44 (0) 121 414 7300
Fax: +44 (0) 121 414 1179
Email: clinchem@ukneqas.org.uk

Parasitology

UK NEQAS Parasitology
Basement 4
The Halo
1 Mabledon Place
London
WC1H 9AZ

Tel: +44 (0)20 3908 1371
Email: parasit@ukneqas.org.uk
Internet
Information about the schemes and intended results and target values of recent distributions are available using URLs:
www.ukneqasmicro.org.uk for microbiology schemes other than the antibiotic assays scheme.
www.birminghamquality.org.uk for antibiotic assays.
These home pages contain links to each other.

Returning your EQA results
Results should be sent via the secure web site accessed through www.ukneqasmicro.org.uk. This web service is password protected; information about the service and your password will be sent to you following registration.
Results returned by fax will be accepted under exceptional circumstances.

Technical support, problems, queries and complaints
To ensure that participants are able to obtain a rapid response and resolution to any complaints, UK NEQAS has an established procedure that will ensure that your complaint is solved rapidly and that the information you supply is used to continuously improve our system. When you contact UK NEQAS, ensure you have your laboratory identification number, and the distribution number and specimen number(s) where these are relevant to your complaint. These identification numbers will be recorded in addition to your name and contact information in case UK NEQAS has need to contact you back. Depending on the nature of the complaint, it may be resolved immediately, e.g. a leaking vial that requires UK NEQAS to replace the specimen, while other complaints may take a little longer to resolve (up to 10 days on average). Details of the complaint are recorded and all information is analysed regularly to identify common problems in our system and implement corrective actions. You can contact UK NEQAS about any complaints, or for any other reason, by phoning, faxing, emailing or writing using the contact information given on page 1. We encourage you to record the details of your complaint, the contact person in UK NEQAS and the relevant date. If you have registered a complaint and have not had the problem resolved within 10 days, you should contact the Organiser.

Introduction
The following explains the operation of the United Kingdom National External Quality Assessment Service (UK NEQAS) for Microbiology. The service is available to both UK and overseas laboratories. Because of regulations in the international postage of diagnostic specimens, overseas participants are mainly supplied via distributors to whom the material is sent by airfreight prior to distribution within a country; where such distribution arrangements apply are listed at the end of this manual. UK NEQAS is always interested in discussing implementation of distribution arrangements in countries not currently covered. In some instances in countries without a distributor, specimens are sent directly to the participant provided all courier charges are paid by the participant.

Nature of the Service
Simulated clinical specimens are prepared in the organising laboratory and distributed to participants with information sheets. Approximately 12 dispatches are made each year and participants receive samples for whatever specimen types they are registered for in each dispatch. Participants examine the specimens in their laboratories and report their findings to the Organiser by web forms. Immediately after the closing date for return of results, brief details of the intended results are made available on the website and a reminder sent by email to participants with e-mail addresses. Replies are analysed and an individual report of the overall results for the distribution is placed on the website accessible through the secure password protected portal; participants are notified by email when the report has been posted on the website. Where 10 or more laboratories within a country participate, information specific to the country is included in the report. Reports are normally available within 10 days of the closing date. Reports that depend on expert commentary, such as Antimicrobial susceptibility, Antifungal susceptibility and Mycology, have an expected turn around time of 30 days.

The Service also runs teaching programmes in blood and faecal parasitology and mycology.
Organisation of the Service

The Service is organised from the external Quality Assurance Department (eQAD) at Public Health England, Colindale. Schemes for parasitology and mycology are organised jointly with the Department of Parasitology, based at the HALO, London and the Mycology Reference Laboratory, Bristol, respectively. All enquiries regarding possible participation in any of the schemes should be made to UK NEQAS for Microbiology at eQAD. The service for antibiotic assays is organised from the UK NEQAS Birmingham Quality, Queen Elizabeth Medical Centre, Birmingham and contact should be made directly with the Scheme Organiser.

Confidentiality

When participants join the schemes they are given a unique code number by which they are identified in all routine transactions. The code may be broken by selected UK NEQAS staff when there is a need to contact a participant for any reason. Except under the very special circumstances outlined under ‘Apparent poor performance’ in the section on additional information for UK participants, the confidentiality of results is strictly maintained and details of the performance of individual laboratories are never revealed to other individuals, nor to any organisation without written permission from the head of the laboratory. However, the fact that a laboratory is registered for schemes is not regarded as confidential and the identity of participants (name of laboratory and Head of Department) may be released at the discretion of the Head of the participating laboratory.

Definitions

It is essential to understand the meaning of two commonly used terms in order to derive the greatest benefit from the schemes. Quality Assurance is the total process by which the quality of laboratory reports can be guaranteed. It is a continual monitoring of working practices, equipment and reagents. It includes such diverse aspects as staff training, provision of methods manuals, checking of media and reagents; in fact all the mechanisms by which the laboratory can be confident of the quality of its reports. Quality Assessment acts as a check on the efficiency of the quality assurance procedures by the introduction of specimens of known but undisclosed content into the laboratory. A failure with a quality assessment specimen often indicates a need to review quality assurance procedures.

Schemes available

The schemes available are shown in the table on page 6. Although every effort is made to ensure continuity of supply of these schemes, no guarantee is made of the numbers distributed in any 12 month period. Participants may elect to receive any combination of these schemes that they wish. The great majority of specimens are straightforward and correspond to those likely to be found in UK clinical practice. Occasionally, more challenging specimens may be distributed for educational purposes or where recognition of an unusual pathogen may be of great importance to the patient or community, e.g. Corynebacterium diphtheriae or Vibrio cholerae. The proportion of positive specimens is higher than that found in routine practice. New types of specimens are introduced from time to time and participants are notified when these become available.
### Schemes available

See schedules for list of accredited schemes.

<table>
<thead>
<tr>
<th>Scheme type</th>
<th>Estimated number of distributions per year</th>
<th>Estimated number of specimens per distribution</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Bacteriology</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>AAFB microscopy</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Antimicrobial susceptibility testing</td>
<td>12</td>
<td>2</td>
</tr>
<tr>
<td><em>Clostridium difficile</em></td>
<td>4</td>
<td>2</td>
</tr>
<tr>
<td>Community medicine</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>Faecal pathogens</td>
<td>1</td>
<td>4</td>
</tr>
<tr>
<td>General bacteriology (identification)</td>
<td>12</td>
<td>3</td>
</tr>
<tr>
<td>Genital pathogens</td>
<td>3</td>
<td>2</td>
</tr>
<tr>
<td>MRSA screening</td>
<td>4</td>
<td>2</td>
</tr>
<tr>
<td>Mycobacterium culture</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Syphilis serology</td>
<td>2</td>
<td>6</td>
</tr>
<tr>
<td>Urinary antigens</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td><strong>Molecular schemes</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CMV DNA quantification</td>
<td>3</td>
<td>2</td>
</tr>
<tr>
<td>EBV DNA quantification</td>
<td>3</td>
<td>2</td>
</tr>
<tr>
<td>HCV RNA detection</td>
<td>3</td>
<td>2</td>
</tr>
<tr>
<td>Hepatitis B DNA quantification</td>
<td>2</td>
<td>4</td>
</tr>
<tr>
<td>HIV-1 RNA quantification</td>
<td>3</td>
<td>2</td>
</tr>
<tr>
<td>Molecular detection of Chlamydia trachomatis &amp; <em>N. gonorrhoeae</em></td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Molecular detection of HEV RNA</td>
<td>3</td>
<td>2</td>
</tr>
<tr>
<td>Molecular detection of HPV</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Molecular detection of mycobacteria</td>
<td>3</td>
<td>2</td>
</tr>
<tr>
<td>Molecular detection of respiratory viruses</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Molecular detection of viruses in CSF</td>
<td>2</td>
<td>6</td>
</tr>
<tr>
<td>Viral gastroenteritis</td>
<td>2</td>
<td>4</td>
</tr>
<tr>
<td><strong>Mycology</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Antifungal susceptibility</td>
<td>3</td>
<td>2</td>
</tr>
<tr>
<td>Cryptococcal antigen detection</td>
<td>3</td>
<td>2</td>
</tr>
<tr>
<td>Fungal Biomarkers</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>Mycology identification</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td><strong>Parasitology</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Blood parasitology</td>
<td>8</td>
<td>1</td>
</tr>
<tr>
<td>Faecal parasitology</td>
<td>8</td>
<td>2/3</td>
</tr>
<tr>
<td>Malaria (Molecular)</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>Malaria rapid</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Toxoplasma serology</td>
<td>4</td>
<td>3</td>
</tr>
<tr>
<td>Parasite serology</td>
<td>4</td>
<td>6</td>
</tr>
<tr>
<td><strong>Virology</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Anti-HBs detection</td>
<td>3</td>
<td>6</td>
</tr>
<tr>
<td>Blood borne viruses</td>
<td>6</td>
<td>3</td>
</tr>
<tr>
<td>Blood donor screen</td>
<td>6</td>
<td>3</td>
</tr>
<tr>
<td>Diagnostic serology – acute hepatitis screen</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Hepatitis B serology</td>
<td>3</td>
<td>6</td>
</tr>
<tr>
<td>Hepatitis C serology</td>
<td>3</td>
<td>6</td>
</tr>
<tr>
<td>Hepatitis E serology</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>HIV Point of Care</td>
<td>4</td>
<td>2</td>
</tr>
<tr>
<td>HIV serology</td>
<td>3</td>
<td>6</td>
</tr>
<tr>
<td>Immunity screen (detection of IgG antibodies to HAV, CMV and VZV)</td>
<td>2</td>
<td>6</td>
</tr>
<tr>
<td>Measles and mumps IgG serology</td>
<td>2</td>
<td>4</td>
</tr>
<tr>
<td>Parvovirus B19 and Rubella serology</td>
<td>2</td>
<td>4</td>
</tr>
<tr>
<td>Respiratory rapid: RSV</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Rubella IgG serology</td>
<td>2</td>
<td>6</td>
</tr>
<tr>
<td>Virus identification</td>
<td>2</td>
<td>4</td>
</tr>
</tbody>
</table>

**Training programmes**

<table>
<thead>
<tr>
<th>No. of courses</th>
<th>Venues</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood Parasitology</td>
<td>9  } Various in the UK and Northern Ireland, and in the Rep. of Ireland</td>
</tr>
<tr>
<td>Faecal Parasitology</td>
<td>9 }</td>
</tr>
<tr>
<td>Mycology (Filamentous fungi)</td>
<td>1 } London, UK</td>
</tr>
</tbody>
</table>
Safety
Any specimen issued as part of the Service may contain fully virulent pathogens (other than hazard group 4, as classified by the Advisory Committee on Dangerous Pathogens, 1995 and the approved list of biological agents 2013). In this respect they are identical to clinical specimens and must be treated with the same degree of caution. They must not be passed on to a third party. This applies to sera as well as to specimens supplied for culture.

Samples are issued to participants on the understanding that they will be used for EQA and that they will be handled by staff trained to handle equivalent clinical samples. The samples are not designed for use in other applications, e.g., for teaching, and participants are cautioned that their use for such purposes may pose safety hazards.

UK participants please note:
Some microorganisms distributed as part of this EQA service are now included in the Schedule 5 list of controlled substances. Storage of any organisms included in the Schedule 5 list following identification requires registration of your facility with the Home Office.

Scoring of results
The purpose of the Service is to help laboratories to monitor their own performance and take action when needed. To assist laboratories in evaluating their performance a scoring system is used with most types of distribution. Generally, a four-point scoring system is used with scores of 2 awarded for correct results, 1 for partially correct results, 0 for wrong results and -1 for grossly misleading results. With some categories of specimens, a decision on whether to score results for a particular specimen is dependent on correct results being obtained by a high proportion of ‘referee’ laboratories selected from those showing good performance in the previous year. Details are provided in the report summary relating to these specimens.

With parasitology specimens, the range of scores obtainable is dependent on the number of parasites in the specimen, with 2 points being awarded for the detection and identification of each parasite and 2 points being deducted for each unexpected parasite reported. Thus, with the current maximum of three parasites included in a specimen the possible score ranges from -6 to +6.

The scoring schemes for general bacteriology, mycology and virus identification are published on our website together with a list of organisms distributed to date, categorised as either core or advanced pathogens.

Assignment of intended results and scoring policy
For the general bacteriology scheme specimens are prepared using known, characterised organisms. Scoring is implemented for specimens when 80% or more of the 100 best performing laboratories (over the previous year, randomly selected by the computer) report a correct result (approx 650 participants).

The mycology scheme is similar except that the 50 best performing laboratories are used (approx 450 participants).

For the other bacteriology schemes, the qualitative molecular schemes and the virus identification scheme no fixed criteria apply. However if less than 80% of laboratories report a correct result the specimen is not normally scored.

For the serology schemes the EQA specimen is characterised using a range of assays and specimens are scored where pre-distribution results concur. Participating laboratories are then scored on their ability to obtain the consensus pre-distribution result; this is relatively straightforward for assays with a qualitative result and when only one assay is used by the laboratory. However for some infections (often those of higher clinical / political / legal importance) laboratories routinely perform more than one assay. In general participants are scored on their overall report for any one disease or marker for that disease.
Special exceptions are made in a few cases, for instance in the syphilis serology scheme Reagin results for syphilis positive specimens are not scored if the Reagin results in pre-distribution tests are negative.

For some schemes, in order to produce challenging specimens, original clinical material is diluted in a suitable base matrix. The approach described, for determining the assigned value, using a range of assays pre-distribution, helps to ensure false reactions due to the specimen matrix are avoided. However this type of pre-selection means that the majority of participants report the correct results (often over 99% correct).

For quantitative serology schemes specimens that give quantitative results close to the cut off are generally not scored if the results are likely to straddle the qualitative result categories. For example rubella IgG specimens with pre-distributions results of antibody levels between 9 and 11 IU/mL are excluded from scoring.¹

For molecular quantitative schemes, due to the variability of quantitative results in terms of absolute values between the assays, proficiency is assessed by comparing performance in terms of the reported difference in concentration between specimen pairs. This strategy is comparable to routine clinical practice where laboratories monitor the effectiveness of patient treatment therapy over time.

**Analysis of performance over a period of time**

The individual report supplied after each distribution also provides laboratories with an individual analysis of their performance over a period of time (6 to 12 months depending on the distribution type).

The following information is presented:

1. A list of the specimens supplied during the period considered.
2. The number of results received too late for analysis.
3. The total score achieved by the laboratory (derived by adding together the scores for each specimen).
4. The total possible score that would have been achieved with a fully correct result in all the specimens.
5. The average score for the series. (The average score for a single specimen is simply the sum of the scores of all laboratories divided by the number of laboratories reporting; the average score for the series is the sum of the average scores of the individual specimens.)

With the above information each laboratory is in a position to compare its performance with that of its peers. If their total score is higher than the average score they are performing better than average. If their total score is lower than the average score their performance is below average. To enable laboratories to quantify how far above or below average their performance is, a further statistic is provided:

The number of standard errors the individual’s result is above or below the average score. This is simply a statistical trick to help identify possible ‘poor performance’, which is defined as a total score more than 1.96 standard errors below the average or mean score.

**Appeals against the evaluation of your performance**

If you wish to appeal against the evaluation of your performance please contact us as described on page 2. Your appeal will be handled according to our complaints procedure. Any errors made by UK NEQAS in assigning your results will be rectified and an amended report issued. Disagreements with the intended results or the scoring policy will be reviewed on an individual basis. Cases which cannot be resolved by discussion with the Scheme Organiser will be referred to the Steering Committee or National Quality Assessment Advisory Panel.

**Reliability of the specimens**

As laboratories use the quality assessment specimens as a benchmark against which to judge their performance it is obviously important that the specimens are reliable. The specimens are subjected to rigorous quality control in the organising laboratory. As an example, batches of specimens for general bacteriology are

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¹ At the time of publishing, debate continues regarding the cut-off level and performance of kits regarding rubella immunity. Participants will be kept updated when required.
sampled both before the distribution and during the distribution period. Duplicate sets of specimens are returned through the post from various laboratories and these are cultured in the organising laboratory. It is not possible to state categorically that every single sample of the specimens is in perfect condition, as quite random events such as unexpected loss of vacuum in a vial between dispatch and receipt can adversely affect viability. It is, however, certain from the quality control sampling that the probability of these events occurring is low and therefore laboratories are unlikely to receive unsuitable specimens. Occasionally, against all expectations, quality control checks during the distribution period reveal unexpected changes in the specimen to an extent where the likelihood of obtaining a correct result is significantly reduced. In these cases participants are always informed of the problem and laboratories’ scores for these specimens are not included in the calculation of performance statistics.

Availability of repeat specimens
Except in cases where material is in short supply, e.g. some serological specimens, repeat specimens are usually available free of charge to laboratories failing with the original. It is very important for laboratories to investigate causes of failure with quality assessment specimens, and repeat specimens should always be requested in such cases. Participants are requested to use the repeat request form on the website so that we can monitor the benefit derived from the service.

Return of results
For most distribution types three weeks are allowed between the UK dispatch date and return of results. This lengthy period is necessitated by the possibility of specimen shipment delays. There is a temptation to spend longer on quality assessment specimens than on routine specimens and participants should satisfy themselves that results are produced in time to be clinically relevant. Airfreight consignments are usually dispatched one week before the UK distribution date to allow time for redistribution. Results returned after the close of the distribution and following publication of the intended results will be recorded as not returned.

The management of the Service
The management of the Service is the responsibility of the Organiser. For the Service to be useful to participants it is essential that there is a wide range of advice and comment available to the Organiser. This is provided by an Advisory Panel and a Steering Committee, both consisting of experienced microbiologists representing the interests of the laboratory community.

Advice is also sought by the Organiser on a regular basis from various experts in particular specialist fields.

Quality and accreditation
The schemes aim to offer a high quality of service to participants and work to objective and measurable quality standards. UK NEQAS for Microbiology, operated by Public Health England, and Public Health England, operating UK NEQAS for Parasitology, are UKAS accredited Proficiency Testing Providers, No. 4715 and No. 7512 respectively. The Antibiotic Assay Schemes are UKAS accredited, reference number 7860.

Charges
The costs of organising the Service are entirely met from subscription charges. The Service is non-profit making and any surplus income is used to expand and improve the services offered. Subscriptions cover participation from April to March and are payable in advance. Participants are sent a record of the various specimen types for which they are registered in January or February each year and invited to notify UK NEQAS of any changes in requirements. Invoices are raised by the host organisation, Public Health England and sent in April or soon after and payment is due within 30 days. Refunds are not normally made if a participant withdraws from participation after invoices have been issued. Subscription charges are reduced pro rata for participants joining the scheme part way through the year.

A list of current subscription fees is available from the Organiser or from your local distributor where applicable.
Additional information for UK and Irish participants

Apparent poor performance

It is intended that participants use the data provided on their report to monitor their own performance and to take any action required as problems are revealed. A ‘back-up’ procedure is used to bring errors to the attention of participants where for any reasons the above measures have been unsuccessful. This procedure is only applicable to UK and Irish clinical laboratories. The procedure used for general bacteriology, antimicrobial susceptibility testing is as follows: every 6 months, in March and September, each participant’s performance during the previous 6 months is evaluated in the organising laboratory. If analysis shows a participant’s total score to be more than 1.96 standard errors below the mean, and if analysis following the next six month’s participation shows a participant’s total score again to be more than 1.96 standard errors below the mean then the results are presented to the National Quality Assessment Advisory Panel for Microbiology. This Panel comprises experienced microbiologists who are nominated by the Association of Clinical Pathologists, the Association of Medical Microbiologists, the Institute of Biomedical Science, the Microbiology Society, the Association of Clinical Microbiologists, the Clinical Virology Network, the Royal College of Pathologists and the Royal College of Physicians, Ireland. At this stage the Panel members are not aware of the names and addresses of the laboratories concerned, which are identified only by their individual code number. The Panel members then review the performance of these laboratories and if they agree that performance can be considered poor the Organiser of the Scheme is requested to send a letter and a copy of results to the participants concerned. Although the Panel members write the letter, they are unaware of the identity of the laboratory and the letter is therefore addressed and posted at the organising laboratory. The letter points out the poor performance in the period concerned and offers help and advice, which can be obtained by contacting any Panel member. The great majority of laboratories approached in this way improve their performance over the next 6-month period and are not brought to the Panel’s attention again. Rarely, laboratories may be poor performers in 3 or more consecutive 6-month periods. In these cases, if the laboratories concerned have not already contacted the Panel, the name and address of the laboratory is revealed to the Panel Chairman or, if the laboratory is from the Republic of Ireland, a representative from the Royal College of Physicians, Ireland. The Chair or representative writes personally to the consultant in charge, again offering help and advice. Performance assessment for other distribution types including mycology, mycobacterium culture, AAFB detection, virology and parasitology follows the same procedure except that performance is reviewed over 12 months rather than six due to the less frequent distribution of samples.

Results from all established specimen types are subject to review by the Panel. New schemes are normally piloted for a year before results become subject to Panel review.
Investigation of failures with EQA specimens

Introduction
These notes are intended to provide participants in the UK NEQAS for Microbiology with some guidance on the investigation of failures with EQA specimens. The examples given are mostly from bacteriology, but the basic principles will apply to other areas. The author appreciates that many participants in the schemes have considerable recent experience of clinical microbiology and their laboratories have excellent quality systems. However, the appropriate response to problems revealed by EQA schemes may be outside of the experience of more recent participants, and these notes may be helpful.

External quality assessment is only one component of a quality system. Some definitions may help to define the relationships between the components.

- **Quality assurance** is the total process whereby the quality of laboratory reports can be guaranteed.
- **Internal quality control** (IQC) comprises the processes carried out to check that media, reagents and equipment are performing within specifications.
- **External quality assessment** (EQA) is the challenge of the effectiveness of a laboratory’s quality system with specimens of known but undisclosed content.

A comprehensive quality assurance system will cover such areas as provision and control of standard operating procedures, education and training, planned maintenance and calibration of equipment, monitoring of response times. Many laboratories are formally accredited to acknowledge conformance with defined and objective quality standards such as those in ISO 17025 or ISO 15189.

Results of consistently good quality can be expected only when all the components of a quality system are in place. This seems a daunting task to those starting along the quality path, but the process is incremental, and every quality component added will help to improve the situation. However, the following limitations are self-evident:

- EQA is not a substitute for other components of the quality system, and in particular, EQA cannot replace IQC.
- EQA is of limited value without at least some of the other quality components such as adequate documentation, training of staff and IQC.
- Most failures with EQA specimens are a result of inadequacies in the other components of the quality system.
- EQA tells you that you may have a problem, it does not solve the problem.
Management issues
EQA is a tool to help senior laboratory staff to identify possible problems in the laboratory. The aim is to provide management with an insight into the quality of the routine work of the laboratory. The following qualifying factors apply:

- EQA results only give an insight into routine results if EQA specimens are treated identical to clinical specimens.
- If EQA specimens are given special treatment, EQA results may be good but nothing will be learnt about the quality of the routine service and patient care will be compromised.

There are several ways in which EQA specimens may be given ‘special’ treatment. They may be handled by more senior grades of staff or subjected to a greater range of diagnostic procedures than normal or results may receive special scrutiny before submission. These practices should be discouraged by laboratory management.

Management need to be sensitive in the way that they deal with failures with EQA specimens. Problems may arise from failures in the quality system rather than from errors by staff. If too heavy handed an approach is taken, staff will become defensive and will take more effort with EQA samples in future to avoid further criticism. Quality systems will not be effective unless the laboratory staff feel a sense of ‘ownership’. For this reason, it is essential to involve staff closely in the process of quality system development. A positive approach to EQA, with regular meetings to discuss results and emphasis on the educational aspects will do much to reassure staff.

How reliable are the UK NEQAS specimens
An initial response to failure with an EQA specimen may be ‘there was probably something wrong with the specimen’. It is of course not possible to guarantee that every single sample of a batch of EQA specimens is representative of the batch as the only way to do this would be to examine every specimen before issue. However, stringent manufacturing practices, past experience with the stability of the specimens and sampling of the batch within UK NEQAS does provide good assurance that it is unlikely that a participant will receive an unrepresentative specimen. Even if a participant does receive such a specimen by chance, it is statistically extremely unlikely that they will receive a series of them.

With serum specimens, occasional artefactual problems are encountered with some kits due to changes in the matrix caused by rethrombinisation of plasma or dilution. Such problems are usually resolved by joint investigation by the manufacturer and UK NEQAS for Microbiology.
The philosophy of UK NEQAS for Microbiology

The schemes are educational; they are not designed to be punitive or for use in licensing of laboratories. The specimens are mostly straightforward; they are not designed to be ‘tricky’ or to catch people out. The specimens will mostly reflect what you are likely to find in routine specimens in your laboratory; however the proportion of ‘positives’ is of course greater in the EQA specimens. Occasionally, a more difficult or unusual specimen may be included in order to give participants the opportunity to gain experience but these specimens are normally not scored.

The objective of the schemes is to allow participants the opportunity to learn from failures. It is not expected that participants should obtain correct results with all specimens; in fact a 100% success record might be viewed with some suspicion!

On receipt of the specimens

● Decide if the specimen is relevant to your normal practice. It is possible that some types of specimen or specimens with a particular clinical history would not be examined in your laboratory. In such cases the reply form should be entered/marked as ‘not examined’. You may decide to examine the specimen for training or educational purposes but there is little point in reporting the result as it will not mirror your routine practices.
● Ensure staff read the information sheet and web instructions carefully for special procedures and any changes from previous distributions.
● Try and make sure that the specimens are handled by the normal staff using routine protocols. Treat them in the same way as you would an equivalent patient specimen with a similar clinical history.
● Keep records of your results to help investigation of any errors.
● Keep any remaining specimen material in case that you need to investigate failures, this may save you time as an alternative to requesting a repeat specimen from UK NEQAS. Follow the storage guidelines received with each distribution. Stability of samples, however, cannot be guaranteed and a repeat specimen from UK NEQAS may be needed.

On notification of the intended results

Intended results are published on the secure area of the website usually the day following the close of each distribution. E-mail notification of the posting of the intended results is available to participants supplying their e-mail address. Compare your copy of the reply form with the intended results and decide if any repeat specimens need to be ordered to investigate discrepancies. Decide if immediate action is necessary or whether investigations should wait until your individual distribution report is published. Generally, it is best to perform at least an initial investigation as soon as possible because as time passes it becomes more difficult for the staff involved to remember events.
On receipt of your report

Reviewing failures with individual specimens

- Read the distribution report to see if many other participants failed with the specimen and for relevant comments made in the report.
- Review all your results with the laboratory staff including successes as well as failures. Ensure that results are available to all, preferably through a ‘quality notice board’.
- Keep records of your reviews and the reasons for any decisions made. File them where they can be retrieved for future reference. The availability of such records will demonstrate your responsible approach to quality to accreditation bodies.
- Complete and submit a UK NEQAS incident review form for inclusion into any poor performance analysis.
- If there are discrepancies, decide if they are relevant.
  - In some cases you would not expect ever to encounter the organism included in your laboratory.
  - In other cases, you would not normally look for the organism in that type of specimen because you consider it not relevant. You may wish to review your procedures in such cases to satisfy yourself that they are still in line with common practice.
  - Full typing, e.g. of viruses, may not be relevant to your normal practices.
  - If you are satisfied that the results are simply not relevant to your circumstances, then you do not need to take any further action other than recording the reasons for your response.

- The score awarded is intended to provide you with a management tool. It allows comparison of your results with that of the ‘average laboratory’ and also serves to bring individual discrepancies to your attention. The allocation of a score is a means of bringing to your attention differences between your report and what has been designated as the ‘correct’ result. In most cases there is little argument about the appropriateness of the score but there will always be differences in laboratory practice both within and between countries that will mean that the score may not be totally applicable to a particular situation. The scoring scheme is regularly reviewed by an advisory panel of UK microbiologists to ensure that it remains relevant to UK practice. Scheme organisers are always pleased to hear the views of participants on problems with the scoring system but in many cases it has to be recognised that no scoring scheme can be universally applicable or relevant.
- If you did not order a repeat specimen when you viewed the intended results, decide if one might be useful and if so order it from UK NEQAS.
- Define what the actual error was. Did you fail to isolate a pathogen, fail to identify, misidentify or, misquantify it, report an incorrect sensitivity profile, fail to detect an antibody, report a false positive result or an unexpected result? Was the probable cause of the error one of technique or of interpretation? Depending on the answer to these questions, you may need to look at your procedures for specimen processing and preparation, your culture conditions, your tests (characterisation, IF, EIA, PCR...), your criteria for interpreting technical results, or reporting procedures.
- Try to follow an audit trail. Can you identify what batch of media, antisera or any test kit you were using? Was it within the specified shelf life? What were the IQC results on that batch of media or kit? In the case of serological and molecular assays, were the controls of the batch in which the EQA specimens were tested within specifications? Who handled the specimen and who authorised the report? Any laboratory with a serious interest in the quality of patient care needs to ensure their quality systems can provide these answers both for EQA specimens and, more importantly, with patients’ samples.
- If you have saved the original specimen or have obtained a repeat specimen then re-examine it. Are there still problems? Is the pathogen growing poorly on your media? Are agglutination or any test results/reactions weak or doubtful? Are your controls behaving as expected? Have you used negative and positive controls? Have you a collection of similar pathogens or similar clinical samples that you can try out? UK NEQAS may be able to provide you with some similar material or organisms if requested.
- False positive results may be due contamination caused by carry over between adjacent specimens. For any procedure the results for negative controls should be reviewed. For molecular assays, consider results of both extraction step and test run negative controls. With serological assays, check that the condition of the specimen appears satisfactory, e.g. is it cloudy perhaps indicating precipitation of proteins or microbial growth. A common cause of false positive results is incomplete washing of micro-wells and washers should be checked and maintenance procedures reviewed.
False negative results may be caused by failure to add the specimen to the test system. Some pathogens are very labile and you should review whether the specimen was tested immediately upon reception and/or reconstitution. With serological assays, the presence of micro-clots in the specimen may lead to false negative results, especially in automated systems. Such events should be rare with UK NEQAS samples. For molecular assays consider the extraction of the sample; examine the results obtained with the extraction positive control and of the internal control.

For quantitative molecular assays how did your results compare with other users of the same assay? What extraction method was used? What volume of sample was extracted? Was your result close to the limit of detection/quantification of your assay?

Procedures and schedules for maintenance, calibration and monitoring of equipment such as incubators, pipettes, washers, readers, microscopes, immuno-assay systems, extraction and amplification platforms should be reviewed.

Failures with slides for immunofluorescence are often caused by incorrect set-up and maintenance and inadequate control of the fluorescence microscope.

Transposition errors are common with EQA specimens (and also presumably, with clinical specimens). Check that either specimens or results have not been transposed during testing or reporting.

Appropriate action may include:

- Introducing or refining IQC procedures
- Training or retraining of staff
- Introducing or refining stock control
- Altering or formalising specimen work up procedures
- Revising standard operating procedures (or methods manuals)

It must always be borne in mind that single EQA specimens may not be representative of the material that is routinely examined in a laboratory. Strains of bacteria for example can vary considerably in their growth requirements, in their antigenic structure and in their biochemical characteristics. For this reason it is unwise to make major changes such as in the supplier or formulation of tests or media on the basis of results with single EQA samples. Such changes may give better results with the particular EQA specimen but worse results with the majority of clinical specimens. Before such changes are made it is necessary to confirm that the problem revealed is general in nature and this will require further investigation with clinical samples.

**Reviewing cumulative performance**

As well as providing details on performance with current specimens, the individual laboratory reports also give details of cumulative performance over a period of time, normally 6 or 12 months. The data provided shows your cumulative score with the specimens examined in this period, the mean score derived from the results of all participants, and the number of standard errors that your cumulative score is above or below the mean. This provides a useful assessment of your laboratory’s performance relative to that of other participants. By the very nature of a mean, it is inevitable that some participants cumulative scores will be below it on occasions. Consistent performance below the mean, or downward trends are probable evidence of continuing quality problems that need to be addressed. Examine the plots of your performance rating over time to identify the trends. A cumulative score of more than 1.96 standard errors below the mean probably indicates significant quality problems that need to be resolved in order to safeguard patient care.

**On receipt of annual record sheets of performance**

Every year, the results obtained between the periods April to March are reviewed. Participants receive record sheets showing their results in all specimens examined in this period. This is a good opportunity to review performance over the year and to see if there are any problem areas with particular pathogens or samples that have been overlooked. Again, all staff should have access to these results.
Joint Working Group for Quality Assessment in Pathology: Conditions of EQA Scheme Participation

The Joint Working Group for Quality Assessment in Pathology (JWG) is a multidisciplinary group accountable to the Royal College of Pathologists for the oversight of performance in external quality assessment schemes (EQA) in the UK. Membership consists of the Chairs of the National Quality Assessment Advisory Panels (NQAAPs), and representatives from the Institute of Biomedical Sciences, the Independent Healthcare Sector, the Department of Health and UKAS.

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

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

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

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

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

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

8. Laboratories' EQA performance will be graded using a traffic light system; green will indicate no concerns, amber poor performance, red persistent poor performance, with black being reserved for the tiny number of cases that cannot be managed by the Organiser or NQAAP and that have to be referred to the JWG. The criteria for poor performance (amber) and persistent poor performance (red) are proposed by the EQA scheme Steering Committee in consultation with the EQA Provider/Scheme Organiser and approved by the relevant NQAAP.
9. When a laboratory shows poor (amber) performance the Organiser will generally make contact with the participant in accordance with the Scheme Standard Operating Procedure for poor performance. Within 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.
UK NEQAS for Microbiology Terms and Conditions of Participation

1. The UK National External Quality Assessment Service for Microbiology (UK NEQAS for Microbiology), herein known as the Scheme, is hosted by Public Health England (PHE) and operated through the external Quality Assurance Department.

2. Samples distributed as part of the Scheme may contain microbiological pathogens of Hazard Groups 1, 2 and 3 as defined by the Advisory Committee on Dangerous Pathogens (Categorisation of pathogens according to hazard and categories of containment. 3rd edition, London: HMSO, 1995) and specified in 'The Approved List of biological agents', HMSO, 2013. Participants must ensure that their laboratory facilities and expertise are adequate to ensure the safe handling of these organisms during their participation in the Scheme.

3. Membership of the Scheme starts on 1st April each year and continues until 31st March in the next year. If a participant joins part way through the annual period, a reduced fee may be payable reflecting the number of samples to be supplied for that part year. A participant may withdraw from the Scheme at any time, but no refund will be given of fees paid.

4. Each laboratory will be registered under a unique code number. Assessment of individual performance is confidential to the participant and will not be released by the Scheme Organiser to third parties other than under any agreed and defined mechanism for providing counselling to 'poor performers'. However, in instances relating to persistent poor performance or lack of participation where patient care may be compromised the Scheme Organiser is free to pass relevant information to third parties. Participants are free to release information concerning their own individual performance to whoever they wish.

5. All reports, and the data they contain, issued by the Scheme are Copyright and may not be published in any form without permission of the Scheme Organiser.

6. In the event of a participant failing to pay the membership fee by the due date the Scheme Organiser reserves the right to terminate, without notice, the membership of that participant without prejudice to any claim for payment for samples already provided.

7. PHE shall not be liable in any circumstances for indirect or consequential loss howsoever caused, including, without limitation, loss of anticipated profits, goodwill, reputation, business receipts or contracts, or losses or expenses resulting from third party claims.

8. Participants in the Scheme have entire responsibility for all samples distributed to them under the Scheme and all activities carried out by them or any third party in relation to the samples from the time of delivery of the samples.

9. PHE warrants that all work carried out by it in relation to the Scheme will be carried out using all reasonable care and skill. All conditions, terms and warranties implied by common law, statute or otherwise are, to the extent permitted by law, hereby excluded.

10. The liability of PHE to the participant in any annual period resulting from or in connection with the provision of the Scheme by PHE to the participant shall under no circumstances exceed the amount of the annual fee paid by the participant in respect of that annual period.

11. These conditions shall be governed by, and construed in accordance with English law and PHE and the participant submit to the exclusive jurisdiction of the English Courts.
Names and addresses

**General Microbiology Schemes**

**Molecular and Virology**

**Dr Sanjiv Rughooputh**
UK NEQAS for Microbiology
PO Box 63003
London
NW9 1GH
Tel: +44 (0)20 8905 9890
Fax: +44 (0)20 8205 1488

**Bacteriology**

**Dr Paul Chadwick**
UK NEQAS for Microbiology
PO Box 63003
London
NW9 1GH
Tel: +44 (0)20 8905 9890
Fax: +44 (0)20 8205 1488

**Mycology and Special Surveys**

**Mrs Shila Seaton**
UK NEQAS for Microbiology
PO Box 63003
London
NW9 1GH
Tel: +44 (0)20 8905 9890
Fax: +44 (0)20 8205 1488

**Antibiotic Assays**

**Dr Rachel Marrington**
UK NEQAS Birmingham Quality
Queen Elizabeth Medical Centre
PO Box 3909
Birmingham
B15 2UE
Telephone: 44 (0) 121 414 7300
Fax: +44 (0) 121 414 1179

**Parasitology Schemes**

**Professor P L Chiodini**
UK NEQAS Parasitology
Basement 4
The Halo
1 Mabledon Place
London
WC1H 9AZ
Tel: +44 (0)20 3908 1371

**Mycology Scheme Consultant**

**Dr E Johnson**
Mycology Reference Laboratory
Public Health England
Myrtle Road, Kingsdown
Bristol
BS2 8EL
Tel: +44 (0)11 7928 5030
Fax: +44 (0)11 7922 6611

**Members of the National Quality Assessment Advisory Panel for Medical Microbiology**

**Dr S Jerwood**
(British Infection Association)
St Richard’s Hospital
Spitalfield Lane
Chichester
West Sussex
PO19 6SE
Tel: +44 (0)7961 394 265
Fax: +44 (0)1243 831 634

**Professor E Smyth**
(Royal College of Physicians of Ireland)
Department of Microbiology
Beaumont Hospital
Beaumont
Dublin 9
Tel: +353 18 093 000

**Dr L Hesketh**
(ACB Microbiology)
Department of Virology
Manchester Medical Microbiology Partnership
Manchester Royal Infirmary
Oxford Road
Manchester
M13 9WL
Tel: +44 (0)161 276 8853
Fax: +44 (0)161 276 8787
Dr G Horne (Chair)
Royal College of Pathologists
Microbiology Department
Queen Elizabeth Hospital
Gateshead Health NHS Foundation Trust
Sherriff Hill
Gateshead
NE9 6SX
Tel: +44 (0)191 445 3695
Fax: +44 (0)191 445 6183

Dr P Riley
(Association of Clinical Pathologists)
Department of Medical Microbiology
Level 1, Jenner Wing
St George’s Hospital
Blackshaw Road
Tooting
London SW17 0QT
Tel: +44 (0)208 7255707
Fax +44 (0)208 7255694

Dr P Muir
(Clinical Virology Network)
Specialist Virology Centre
Public Health Laboratory Bristol
National Infection Service
Public Health England
Myrtle Road
Bristol BS2 8EL
Tel: +441173425042

Dr M A Zuckerman
(Co-opted Virologist)
South London Specialist Virology Centre
Kings College Hospital NHS Foundation Trust
2nd Floor, Cheyne Wing
Bessemer Road
London
SE5 9NR
Tel: +44 (0)20 3299 6155

Miss C Williams
(Institute of Biomedical Sciences)
Freeman Hospital
Newcastle upon Tyne Hospitals NHS Foundation Trust
Freeman Road
Newcastle upon Tyne
NE7 7DN
Tel: +44 (0)191 244 8897

Steering Committee Members

Susan Benson
Homerton University Hospital
NHS Foundation Trust
Homerton Row
London E9 6SR

Dr P Chadwick
Salford Royal NHS Foundation Trust
Salford
M6 8HD

Professor P L Chiodini
Department of Clinical Parasitology
Hospital for Tropical Diseases
Capper Street, Mortimer Market
London
WC1E 6AL

Dr S Gossain
West Midlands Public Health Laboratory
Birmingham Heartlands and
Solihull NHS Trust
Public Health England
Bordesley Green East
Birmingham
B9 5SS

Dr Katie Hardy
PHE Laboratory Birmingham
Heartlands Hospital
University Hospital Birmingham NHS Trust
Bordesley Green East
Birmingham
B9 5SS

Professor P M Hawkey (Chair)
West Midlands Public Health Laboratory
Birmingham Heartlands and
Solihull NHS Trust
Public Health England
Bordesley Green East
Birmingham
B9 5SS

Dr G Horne
Royal College of Pathologists
Microbiology Department
Queen Elizabeth Hospital
Gateshead Health NHS Foundation Trust
Sherriff Hill
Gateshead
NE9 6SX

Dr E Johnson
Director, PHE Mycology Reference Laboratory
and National Collection of Pathogenic Fungi,
PHE South West Laboratory,
Myrtle Road,
Kingsdown,
Bristol
BS2 8EL
Dr B L Jones
Department of Medical Microbiology
Glasgow Royal Infirmary
Lister Building, 84 Castle Street
Glasgow
G4 0SF

Prof G Kahlmeter
Clinical Microbiology
Central Hospital
35185 Vaxjo
Sweden

Dr Rachel Marrington
UK NEQAS Birmingham Quality
Queen Elizabeth Medical Centre
PO Box 3909
Birmingham
B15 2UE

Mrs Shila Seaton
UK NEQAS for Microbiology
PO Box 63003
London
NW9 1GH

Dr Sanjiv Rughooputh (Secretary)
UK NEQAS for Microbiology
PO Box 63003
London
NW9 1GH

Antimicrobial Susceptibility Testing Specialist Advisory Group

Malcolm Armstrong
Medical Microbiology
Clinical Sciences Building 1
Manchester Royal Infirmary
Oxford Road
Manchester
M13 9WL

Dr Paul Chadwick
UK NEQAS for Microbiology
PO Box 63003
London
NW9 1GH
Tel: +44 (0)20 8905 9890
Fax: +44 (0)20 8205 1488

Dr R Howe (Chair)
NPHS Microbiology Cardiff
University Hospital of Wales
Heath Park
Cardiff
CF14 4XW

Prof G Kahlmeter
Clinical Microbiology
Central Hospital
35185 Vaxjo
Sweden

Dr N Woodford
Antimicrobial Resistance and Healthcare Associated Infections Reference Unit
Public Health England
61 Colindale Avenue
London
NW9 5EQ

Shila Seaton (Secretary)
UK NEQAS for Microbiology
PO Box 63003
London
NW9 1GH

Prof David Livermore
Medical Microbiology
University of East Anglia
Norwich Research Park
Norwich
NR4 7TJ

Virology Specialist Advisory Group

Dr M C Donati (Chair)
Consultant Medical Virologist/Head of Virology
Bristol Public Health Laboratory
Myrtle Road
Bristol
BS2 8EL

Dr Sanjiv Rughooputh (Secretary)
UK NEQAS for Microbiology
PO Box 63003
London
NW9 1GH

Dr P McIntyre
Department of Medical Microbiology
Ninewells Hospital and Medical School
Dundee
DD1 9SY

Elisabeth North
Bristol Infection Sciences Laboratory
Severn Pathology
Bristol
BS10 5NB
UK NEQAS for Microbiology Key Personnel

**Dr Sanjiv Rughooputh**  
Molecular and Virology Scheme Organiser

**Dr Paul Chadwick**  
Bacteriology Scheme Organiser

**Shila Seaton**  
Mycology and Special Surveys Organiser

**Priya Patel**  
Laboratory Manager

**Dr Jaya Shrivastava**  
Parasitology Scheme Manager

**Dr Beatrix Kele**  
Virology and Molecular Scheme Manager
# List of distributors /freight forwarders and addresses

## Austria
**Prof G Wewalka**  
Bundesstaatliche Bakteriologisch-serologische Untersuchungsanstalt  
Währinger Straße 25A  
A-1096 Wien  
Austria

## Belgium
**YVSOLAB**  
Antwerpseweg 193  
2340 Beerse  
Belgium

## Czech Republic
**Dr Helena Zemlickova**  
The National Institute of Public Health  
Srobarova 48  
10042 Prague 10  
Czech Republic

## Denmark
**DEKS**  
54MI Herlev Hospital  
Herlev Ringvej 75  
DK-2730 Herlev  
Denmark

## Finland
**Labquality**  
Ratamestarinkatu 11  
Fin-00520 Helsinki  
Finland

## France
**Centre Suisse de Contrôle de Qualité**  
2, Ch. du Petit Bel-Air  
CH-1225 Chêne-Bourg  
Switzerland

## Germany
**HiSS Diagnostics GmbH**  
Guterhallenstrasse 3  
79106 Freiburg  
Germany

## Greece
**VARELAS S.A. Chemicals & Diagnostics**  
Achilleos 2  
104 37 Athens  
Greece

## Hong Kong & Macau
**Dr D N C Tsang**  
Department of Pathology  
Queen Elizabeth Hospital  
30 Gascoigne Road  
Kowloon  
Hong Kong

## Ireland
**Eurofins Biomnis Laboratories**  
Three Rock Road  
Sandyford Industrial Business Estate  
Dublin A4C0  
Ireland

## Israel
**Rhenium Medical Limited**  
Rhenium Medical Limited  
Hasatat Street, 20  
Einav Center (ADJ to Ishpro Center)  
Mod’in 7171101  
Israel

## Italy
**ThermoFisher Scientific**  
Strada Rivoltana Km4  
20090 Rodano (MI)  
Milan  
Italy

## Kenya and Malawi
**Mr A Grant**  
C/O Carramore International Ltd  
Units 10-11 Thongsbridge Mills  
Miry Lane  
Holmfirth  
HD9 7RW  
United Kingdom
Kuwait  
*Bahman General Trading & Cont Co*  
Shuwaikh Industrial Area PO Box 327  
Safat 13004  
Kuwait  

Netherlands  
*ECAT Foundation*  
P.O. Box 107  
2250 AC Voorschoten  
The Netherlands  

Norway  
*NOKLUS*  
Norwegian Quality Improvement of Laboratory Examinations  
P O Box 6165  
5892 Bergen  
Norway  

Portugal  
*Biognóstica Lda.*  
Praceta das Flores  
No. 7-A  
2610-074 Alfragide  
Portugal  

Romania  
*S.C. Kriticon Corpus S.R.R.*  
Str. Aeroportului nr. 2, Zona A  
Cod postal 013594, Sector 1  
Bucuresti  
Romania  

Slovenia & Croatia  
*Tre-Gi SAS International Trading and Services*  
Via Zangrando 8  
PO Box 809  
34139 Trieste  
Italy  

South Africa  
*The Scientific Group*  
1 New Road  
Midrand  
1682 Gauteng  
South Africa  

Sweden & Iceland  
*EQUALIS AB*  
Kungsgatan 113  
SE-735 18 Uppsala  
Sweden  

Switzerland and Liechtenstein  
*Centre Suisse de Contrôle de Qualité*  
2, Ch. du Petit Bel-Air  
CH-1225 Chêne-Bourg  
Switzerland  

Turkey  
*Karca Medikal Sistemler San.Tic.Ltd.Sti*  
Nacicakir Mahallesi 759.sok  
No:11/4 06450 Cankaya/Dikmen  
Ankara  
Turkey