External Quality Assurance Scheme

Biochemistry



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INTRODUCTION

EXTERNAL QUALITY ASSURANCE

Although monthly internal quality control is very important in determining the day-to-day performance of a biochemistry analyser, External Quality Assurance schemes have the advantage of comparing individual laboratories with others using the same method. This is essentially an assessment of accuracy and precision, with the mean value of the participating laboratories being used as the 'true' value of the analyte.

How the Scheme Works

A series of unknown samples are distributed to the participants of the scheme, and each practice laboratory analyses the samples one at a time, on a specified date, for a specified profile. The results are then sent back to the scheme organizers for statistical analysis. The results are kept strictly confidential and are not disclosed to any third party.

'Wild' results are identified so that we can eliminate any 'outliers'. These results are usually either due to faulty analysers or transcription errors, and it is important to eliminate them to prevent distortion of the mean and SD calculations.

The practice laboratory's submitted result for each analyte is then compared with the final mean and SD of the participant's results. The deviation of the result from the mean is then calculated and expressed in standard deviations from the mean. As with the internal quality control, the result should be within 2SD's of the mean.

What Happens If There Is a Problem

If a practice laboratory appears to have submitted poor results, then the Scheme Supervisor or the Technical Support team will contact your practice. Many problems occur because of poor reconstitution of the control material, so it is important to follow the written protocol closely.

'**Wild' results** often occur due to transcription errors, and if such an error has been made, please inform the organisers so that the result can be changed on the participant's file.

Inaccuracy occurs when all the results are to one side of the mean, and this is known as a systematic error. The Scheme Supervisor will help in identifying the cause of these errors.

Imprecision occurs when the results appear to be widely scattered, and this is known as a random error. These errors are usually due to an inconsistency in the procedure, such as inadequate mixing of the control material itself, or delay in analysing the sample. The Scheme Supervisor will help in identifying the cause of these errors and will advise on how to overcome the problem.

As part of EQA membership you have access to the Scheme Supervisor & IDEXX Technical Services team, who can offer help and advice regarding EQA issues.

For EQA In-Clinic Technical Advice please contact

Scheme Administrators eqa@idexx.com

Technical Support Advisors: 0203 7887508

QUALITY CONTROL

Quality control can be defined as the action of detecting errors, and there are many potential errors that can affect the quality of results leaving the laboratory.
Errors in analysis can be separated into three groups:

1. **Pre-analytical**
2. **Analytical**
3. **Post Analytical**

1. Pre-Analytical Errors

These errors occur outside the practice laboratory but affect the quality and usefulness of the result obtained. For example, these may include:

- Fasted state of the patient
- Collection of the blood into the correct blood tube
- Proper collection of the blood - a poor blood collection technique may result in haemolysis of the sample, which will affect many tests
- Labelling the blood tubes with the correct patient details

Pre-analytical errors should be minimised by the phlebotomist.

2. Analytical Errors

These errors occur within the practice laboratory, and may be caused by:

- Reagents being stored incorrectly
- Contamination of pipettes
- Improper use of pipettes
- Instruments being improperly maintained
- Transcription errors when entering patient information or when reporting results
- Dilution errors
- Human error - tiredness, carelessness, lack of training
- Improper use of the instrument

Quality assurance schemes are used to assess analytical errors, and it is the area of quality control that laboratory workers have the most immediate control.
The purpose of joining external quality assurance schemes is to assess precision and accuracy within the practice laboratory, and it is therefore important to handle these samples in the same way as you would handle patient samples.

3. Post Analytical Errors

These errors concern the prompt and correct delivery of the correct report, on the correct patient to the correct physician.

The practice laboratory can react and correct analytical errors by using appropriate external quality assurance schemes far more easily than correcting any error outside the immediate laboratory control.

DEFINITIONS USED IN QUALITY CONTROL

1. Accuracy

Accuracy refers to the agreement between the value obtained from an analyser and the 'true' value - i.e. it is a term describing how correct the result is. When using quality control sera, the value quoted by the manufacturer can be taken as the target value, and the closer to this value the result obtained in the practice laboratory is, the better the accuracy.

2. Precision

Precision refers to the 'reproducibility' of the results obtained from an analyser - i.e. the agreement between replicate measurements. The closer the results are to each other for the same component in the same sample, the better the precision.

NB:

It is important to remember that accuracy and precision are totally different. A practice laboratory should aim for good accuracy **AND** precision, so that test results are close to each other **AND** the mean of those results is close to the true value of the analyte.

- **Poor precision** and **good accuracy** results in widely spread results giving poor precision, but the mean of those results is close to the true mean giving good accuracy.

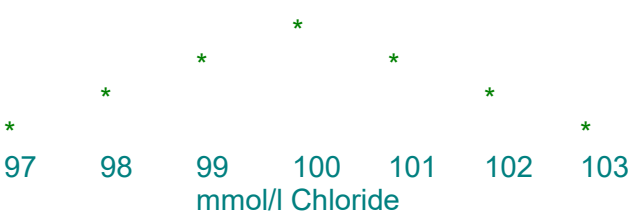
- **Good precision** and **poor accuracy** results in values being close together giving good precision, but the mean of those results is not close to the true mean giving poor accuracy.

3. Gaussian Curve

The Gaussian curve is also known as a Normal Distribution. If an analyte is analysed 100 times by an analyser, and the values obtained obey the laws of probability, most values will fall about the mean value. For example, if the mean of a series of chloride measurements is 100 mmol/l, the distribution of results may be as follows:

97 mmol/l	2 times
98 mmol/l	14 times
99 mmol/l	22 times
100 mmol/l	24 times
101 mmol/l	22 times
102 mmol/l	14 times
103 mmol/l	2 times

This can be expressed graphically as follows:



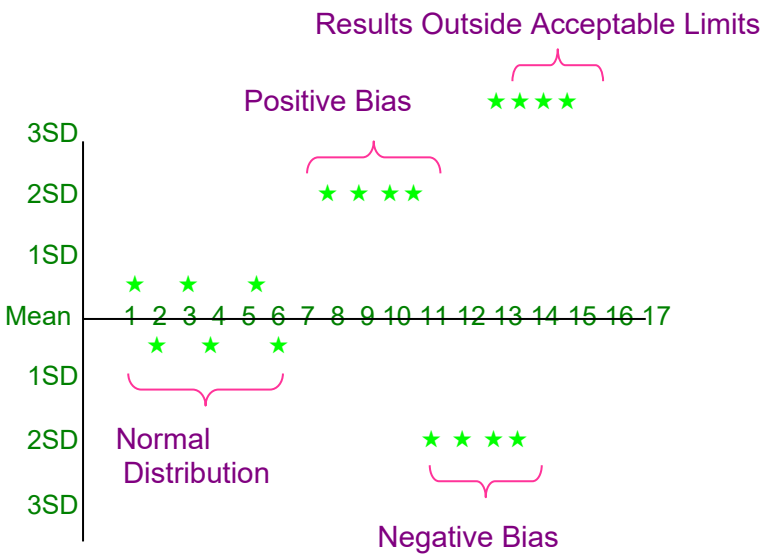
The precision of the method is expressed in terms of how dispersed the values are, and for this the term **Standard Deviation (SD)** is used. The smaller the SD the more precise the result is.
A 1SD range includes 68% of all the values - in the above example it would include all chloride values between 99 and 101 mmol/l. A 2SD range includes 98 % of all the values, which would include all chloride values between 98 and 102 mmol/l.

In order to enable the comparison of the SD's of different methods, and therefore decide which tests perform better than others, the **Coefficient of Variation (CV)** is used. This is a simple calculation, which expresses the SD as a percentage of the mean.

4. Levy-Jennings Plot

The Levy-Jennings plot is used to highlight any trends that may be developing in any given method. The SD's of each result for each method are plotted consecutively on separate graphs. If the method is performing well, then the graph should show a normal distribution. If, however, the results fall consistently either above or below the mean for that method, then this indicates that the method has either a positive (results are consistently above the mean) or negative bias (results are consistently below the mean).
The Levy-Jennings plot will also highlight more serious problems occurring with a method – for example, if the results are consistently greater than +/- 2SD's, then the assay performance is outside the acceptable limits, and requires further investigation.

For example:



EXTERNAL QUALITY ASSURANCE SCHEME BIOCHEMISTRY

The purpose of the biochemistry section of the external quality assurance scheme is to assess the accuracy and precision of the Catalyst One, Catalyst DX, VetStat and VetLyte analysers, as well as the competency of participants when:

- Preparing the quality control material.
- Analysing the quality control sample using the Catalyst One, Catalyst DX, VetStat and VetLyte analysers.

Participating practice laboratories will be provided with a pack containing six vials of lyophilised human serum and six vials containing 5mls of diluent. All the vials are sealed under vacuum and should be stored in the refrigerator. Participants will be asked to reconstitute the appropriate vial of serum by carefully adding the full contents of the diluent vial and then leave it to stand in a cool place out of direct sunlight. They will then be required to analyse the reconstituted serum and the results should then be recorded on the result sheet provided and sent to the reference laboratory.

The reference laboratory will process the results received from all the participants and will return answer sheets detailing the following:

- the results for each analyte received from the participant
- the mean value for each analyte calculated using all the results received
- a comment based on the accuracy and precision of the result for each analyte. This will be in the style – Good, Borderline or Outside Range

The results will also be monitored by the laboratory and participants consistently showing Borderline or Outside Range results; or showing either a positive or negative bias will be contacted, and help given to rectify any problems.

Any participants requiring assistance with any part of the scheme may contact the reference laboratory and help will be provided. The following online courses can be found at the **IDEXX Learning Center** (www.idexxlearningcenter.com) and may be useful in assisting with the biochemistry assessments:

- Learn More about the Catalyst DX Analyser: (https://www.idexxlearningcenter.com/idexx/user_activity_info.aspx?id=355)

- The VetStat Electrolyte and Blood Gas Analyser Certificate Course (https://www.idexxlearningcenter.com/idexx/user_activity_info.aspx?id=1000)

An example of the biochemistry assessment document is as follows:
(Example shown is for Catalyst analyser)

IDEXX LABORATORIES
EXTERNAL QUALITY ASSURANCE SCHEME
BIOCHEMISTRY ASSESSMENT

1.0 DISTRIBUTION PACKAGE

1.1 This distribution package included a box containing six bottles of lyophilised serum samples numbered 1 to 6 and six bottles of diluent.

1.2 Every two months you will receive a new biochemistry assessment with a sheet to return you results. An instruction guide on how to complete the biochemistry assessments will be also attached.

2.0 INFORMATION FOR CONTROL OF SUBSTANCES HAZARDOUS TO HEALTH (COSHH)

The serum is human based. It has been source tested and found to be negative for HbsAG and antibodies to HIV. For complete protection however, it is recommended that the serum should be handled according to the protocol in force for the safe handling of patient samples within the practice and should be disposed of as such.

3.0 USE OF PACKAGED MATERIAL

The material supplied is intended to be used as part of the external quality assurance surveys in order to aid the accurate and precise analysis of blood samples using In-Clinic equipment within the practice.

4.0 PREPARATION OF THE QUALITY CONTROL SERUM

The biochemistry serum should be prepared according to the following protocol:

- Select **SAMPLE NUMBER 1** of lyophilised serum for the survey reference under analysis, and also select a vial of diluent.
- The vials are sealed under vacuum. Open both vials very carefully, avoiding any loss of material from the lyophilised sample.
- Reconstitute the lyophilised serum by **carefully adding the FULL contents of the diluent vial to the vial containing the lyophilised sample.**
- Replace the rubber stopper to the vial of lyophilised serum and leave to stand for 60 minutes in **a cool place out of bright sunlight** before use.
- Ensure that the lyophilised contents are completely dissolved by **swirling the vial gently every 10 minutes** during the reconstitution period. **Do not shake the vial**.
- **Analyse the serum immediately** after reconstitution.
- **Select "Adult Canine" for the analysis**

5.0 ANALYSIS OF THE QUALITY CONTROL SERUM

The quality control serum should be analysed for the chemistries in the Chem17, Lyte4, TT4 (optional) and SDMA (optional) CLIPS. These are:

ALBUMIN
ALKALINE PHOSPHATASE (ALP)
ALT
AMYLASE
UREA
CALCIUM
CHOLESTEROL
CREATININE
GGT
GLUCOSE
LIPASE
INORGANIC PHOSPHORUS
TOTAL BILIRUBIN
TOTAL PROTEIN
SODIUM

EXAMPLE

POTASSIUM
CHLORIDE
TT4 (optional)
SDMA (optional)

5.1 Please do NOT dispose of the reconstituted sample. The sample should be stored in the FREEZER for up to ONE MONTH. This is in case it is necessary for you to re-run the sample, which can be done (following defrosting) anytime up to a month after reconstitution.

5.2 Please note if you do not save and receive the reconstituted sample and a "re-run" is necessary you will be charged for the cost of sending an additional sample.

6.0 REPORTING RESULTS

6.1 The results should be recorded on the sheet provided.

6.2 Please ensure that the CORRECT UNIT (as indicated on the result sheet) are used when recording the results.

6.3 Before returning the results sheet, please ensure that your practice veterinary code is clearly marked. Result sheets without this code cannot be processed by the laboratory.

6.4 Please return your results sheet to:

Email: karen-choi@idexx.com or eqa@idexx.com or via VetConnect+

Please mark your result sheets for the attention of: **KAREN CHOI**

6.5 The result sheets will be processed by the laboratory, and each practice will receive a report sheet.

7.0 RESOURCES TO HELP YOU COMPLETE THE BIOCHEMISTRY ASSESSMENT

7.1 Visit www.idexxlearningcenter.com and choose 'On Demand'. Here you will find a range of online courses including:

- Learning More about the Catalyst Dx Analyser
- The VetStat Electrolyte and Blood Gas Analyser Certificate Course
- The IDEXX VetLab Station Certificate Course

The above online courses enable you to download a CPD certificate upon completion.

(Please note you are required to create a username & password to access these resources. These resources are all free of charge for customers of IDEXX Laboratories)

EXAMPLE

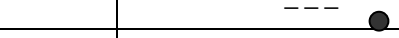
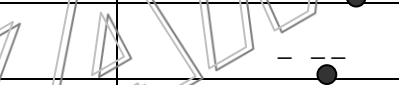
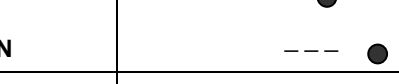
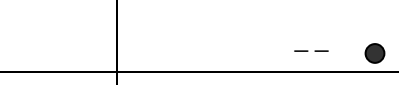
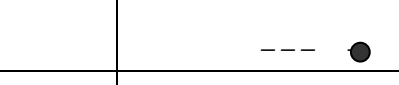
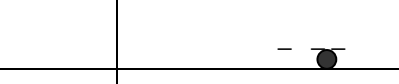
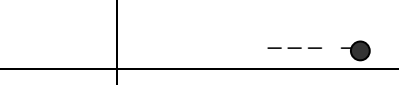
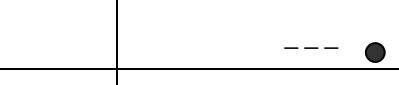
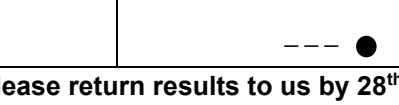
BIOCHEMISTRY ASSESSMENT 1 - RESULTS

SAMPLE NUMBER 1

Practice Name: _____

Vet Code: _____

Survey Reference: 23.1

ANALYTE	CATALYST DX RESULT	UNITS
ALBUMIN		g/l
ALKALINE PHOSHATASE		U/l
ALT		U/l
AMYLASE		U/l
UREA		mmol/l
CALCIUM		mmol/l
CHOLESTEROL		mmol/l
CREATININE		µmol/l
GGT		U/l
GLUCOSE		mmol/l
LIPASE		U/l
INORGANIC PHOSPHATE		mmol/l
TOTAL BILIRUBIN		µmol/l
TOTAL PROTEIN		g/l
SODIUM		mmol/l
POTASSIUM		mmol/l
CHLORIDE		mmol/l
TT4 (optional)		nmol/l
SDMA (optional)		µg/dL

EXAMPLE

**** Please return results to us by 28th February**
Any results received after this date may be reported as "no results" **

EXAMPLE REPORT SHEET

IDEXX
GRANGE HOUSE
SANDBECK WAY
WETHERBY
WEST YORKSHIRE
LS22 4DN

Tel
UK +44 (0) 2037887508
EIRE: +352 (0) 15621211

Ferbruary 2023

EXAMPLE

CATALYST EQAS G55
Survey Reference Number 23.1

Analyte	Optics Grp	Your Val	Mean	Comment
ALBUMIN	3	27	27.82	Good
ALP	5	253	249.38	Good
ALT	4	140	151.12	Good
AMY	2	177	159.41	Good
BUN	3	18.5	18.67	Good
CALCIUM	6	3.03	3.04	Good
CHOL	2	6.68	6.82	Good
CREAT	3	365	373.54	Good
GGT		134	130.10	Good
GLUC	2	15.06	15.31	Good
LIP		808	824.18	Good
PHOS	3	2.07	2.09	Good
BILI	2	77	77.75	Good
PROT	2	50	49.54	Good
SODIUM	Elec	166	164.04	Good
POTASSIUM	Elec	6	6.56	Good
CHLORIDE	Elec	124	123.38	Good
TT4		129	122.69	Good

Please find enclosed the biochemistry report sheets for sample 1of the 2023 External Quality Assurance Scheme.

The report shows your result, the mean value of all the results received and a comment on your result based on the statistical evaluation. If the comment is good, your result is within the acceptable limits and no further action is required Borderline results are still acceptable but will be monitored on future returns to ensure that a trend is not developing.

Results that are outside range are not within the acceptable limits, and I will be contacting you shortly, so that any problems you may have are rectified.

If it is “no result”, this indicates we have not received any results for this sample. If you have a copy you can send themto eqa@idexx.com and we will process these for you.

If you require further information or assistance in the meantime, please do not hesitate to contactkaren-lumb@idexx.com.