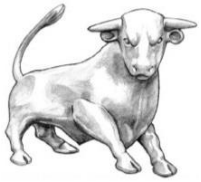

Birmingham Quality

UK NEQAS
International Quality Expertise

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B15 2UE

for the attention of all our valued Participants and Distributors

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Monday 18 May 2020

Birmingham Quality Point of Care Suite Resumption of Distributions

All of our regular UK NEQAS Laboratory services are essentially running 'Business as Usual'.

That said, you may not be aware that we also have a number of services out-with the regular laboratory settings that are targeted towards walk-in clinics and pharmacies and the like. These providers are reviewing their services generally, not least because of reduced footfall, social distancing and taking blood for their services.

The good news is that after liaising with some of the major players we intend, wherever possible, to resume normal service for our June Distributions for the Birmingham Quality Point of Care Suite.

Once again we thank our participants for continuing to use our services through these difficult times

Invoicing for Laboratories

We are now invoicing Laboratories for 2020-2021 based on their own on-line renewal submission.

So, Stay Safe, Be Alert and Pay your Bill ☺ !

Finlay MacKenzie

Finlay MacKenzie, Director Birmingham Quality

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Monday 11 May 2020

Birmingham Quality Be Alert and Be Safe, wherever you are

All of our regular UK NEQAS Laboratory services are essentially running 'Business as Usual'.

Following the Prime Minister's broadcast yesterday, it looks as if the devolved governments are taking a slightly different approach to the UK Government. Nevertheless the overall impact on NHS Laboratories across the UK remains essentially unchanged.

We still have our share of operational challenges as I'm sure you have, too.

This update is just to reassure our Participants that we are still here and still doing our best to offer you our world-class EQA provision.

Invoicing for 2020 – 2021

The only fresh bit of news that we have is that we have processed all of the on-line re-registrations and are going forward with our formal Invoicing. Most Participants had completed theirs and had provided a matching Purchase Order Number. Many thanks for this. Those of you who haven't managed to sort things out yet, you must check your quotation (which is under your "Lab Button" on the Results and Reports web entry page) and get back to us ASAP with a PO number or with any changes that you haven't updated us with. Participants whose finance department will pay without the requirement of a PO number should inform us of this, please.

Once again we thank our participants for continuing to use our services through these difficult times

Be Alert and Be Safe (and pay your bill!), wherever you are!

Finlay MacKenzie

Finlay MacKenzie, Director Birmingham Quality

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Tuesday 21 April 2020

Regular Update

As far a Birmingham Quality is concerned we are essentially running 'Business as Usual' and this week should be no exception.

We, like you, are working hard to keep our NHS Service running and have our share of sick staff, self-isolating staff, home working staff and staff in shielding but we are determined to keep our Participants happy. We are socially distancing which does make specimen production a little challenging!

We have extended the closing dates for both Participants and Assessors for the UK NEQAS for Interpretative Comments but our all our Specimen-based services are continuing according to our published schedule which you can find here on our website.

So this week we will dispatching our Steroid Scheme (with its harmonised 3-specimen model), GFR, Newborn Screening, Vitamin D and Paediatric Bilirubin.

We will keep our Participants up to date with any developments but in the meantime, Stay Safe!

Kind regards

Finlay

Finlay MacKenzie

Finlay MacKenzie, Director Birmingham Quality

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Wednesday 1st April 2020

Covid-19 No penalty for Late returns

We are trying to keep our core services running as close to normal as can be expected under the difficult position we find ourselves in.

Laboratories often worry about getting 'Performance Letters' and the like from EQA Organisers for not returning results on time or for not returning results at all. I would like to reassure Participants that for the foreseeable future, though our electronic systems continue to collect such data, we will not be penalising you.

All we would ask is that if you do return results after a Distribution has closed because of staffing/logistical issues with Covid-19, if you could please just state 'Covid-19' in the comments/reasons box. We will be collating this data at the anonymised/screening/population level to assess the impact, but we will not be penalising you/your lab individually.

If you do not intend to return results at all for a Distribution, there is a check box you can tick on the Data Entry screen. Please just put 'Covid-19' in the comments box.

☐ Tick this box if you have no results at all for this distribution; you must provide a brief explanation in the comments box below

Stay safe!

Many thanks

Finlay

Yours faithfully

Finlay MacKenzie

Finlay MacKenzie, Director Birmingham Quality

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Friday 27 March 2020

Covid-19 and the Birmingham Quality Response

Though different EQA Schemes and providers will all have specific ways of doing things and will have different pressures and priorities, I thought it might be helpful to provide some insight on the Birmingham Quality approach to how and what we are doing in these strange times.

In particular, many participants are asking us about Risk Management and whether they should or shouldn't be running EQA. The following notes give a flavour of our approach and is in no way meant to be a wholly comprehensive answer to all situations.

By and large, for our schemes, there are two different scenarios.

[1] You have suspended clinical services for Analytes X, Y and Z and since you won't be running assays, you will not be needing EQA.

This is fairly non-contentious. In the past when life was straightforward, many Labs kept up their EQA so while they did troubleshooting and were re-optimised their assays on stored specimens. This meant that before they restarted their clinical work, they could be assured of how their assay was performing. I would be content if Laboratories didn't keep up their EQA under current circumstances.

[2] You are continuing with clinical services for Analytes X, Y and Z but have decided that you won't be doing any EQA. If you decide to take this approach then the Risk Management process has to look at a number of features.

In addition to the EQA-specific points below, any Risk Management of your service needs to consider your IQC practices, equipment maintenance, training and competencies of staff running the service now and any business continuity plans that you may be implementing. You will also have to take into consideration the impact on your current ISO15189:2012 accreditation. Conversations we have had with Laboratory Managers would suggest that there is concern about patient safety if too many corners are being cut and we are actively being asked by many Participants to run as full a service as possible. Please refer to the Birmingham Quality website where regular updates are being posted. I am pleased to reassure you that we have full, comprehensive business continuity plans ourselves.

If it is the staffing overhead of the mechanics of handling EQA samples, rather than the absolute numbers of additional tests you are doing that is the issue then using our NPEx solution will mean that our samples arrive already logged into your system and all you have to do is attach a barcode or swipe our RequestCard/Manifest and the specimens get processed and the results come back to us without any further manual intervention from yourselves.

If it the capacity of your analyser in having 3 EQA specimens a month against a backdrop of 2000 patient specimens a day, then it is a different set of considerations.

Westgard is currently looking at using sophisticated tools to assess what level of IQC a Lab should be running to put effort into those that carry the biggest risk in terms of getting a wrong result and a patient being misdiagnosed or pushed down the wrong clinical pathway. The same could be true for EQA. We know that for some assays there are huge batch-to-batch or lot-to-lot variations which are **not** picked-up using the matched IQC that manufacturers provide. The issue for most Labs is usually not how much 'wobble' is there in your assay across a long shelf-life set of reagents/calibrators, but what differences you see on changing lots and batches of reagent or calibrator or software or following cleaning or maintenance.

The majority of our assays are performed in huge numbers on large throughput analysers and we think it is important that you have that extra reassurance of EQA.

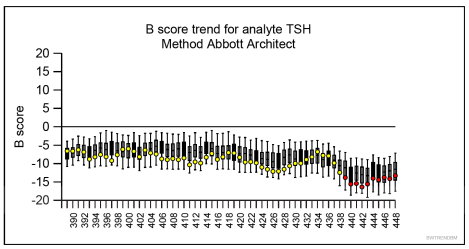
Some assays by their very nature are new, technically demanding and have no clear reference ranges, reference methods or national guidelines as to their use. For something like Faecal Calprotectin, I would say that this assay needs a lot of thorough

QA measures which would include regular EQA *(not withstanding that some Labs have concerns about potential viral load in non-serum specimens)*. For something like Serum Indices which can affect almost all analytes and where IQC is scant, if present at all, EQAS is all the more important. For something like sodium or creatinine you *might* have very tight assays and could risk assess frequency of IQC, on the other hand you may not. You should be plotting your IQC in units and in %bias as well as in SD differences. SD differences have limited use in EQA despite their widespread use. Unfortunately, in our experience though there is much IQC sample measurement being performed by Labs across the country, the data crunching as to what it means isn't usually done that well.

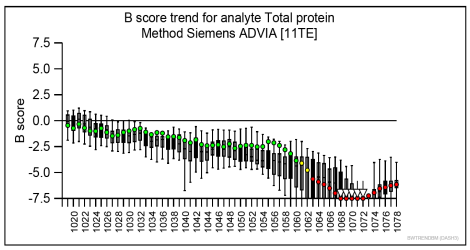
As the stocks and shares investment houses legally have to say upfront, good performance in the past is no guarantee of good performance going forward, but there are things you can do to mitigate matters.

Our Seismograph plots show that even well-established methods for mainstream analytes can shift out of consensus. Look at these examples from major players for TSH and Total Protein. Likewise, look at the spread of biases for Free T3, even when the target is the Instrument Box mean.

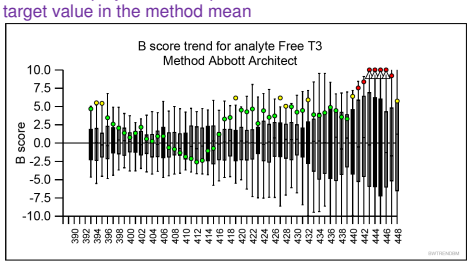
Method moves more negative



Method moves more negative



Method displays a wide spread of biases even when the target value in the method mean



For UK NEQAS Birmingham Quality Schemes the default position is to assess each 'box' with 3 specimens per month. Note: This is not the same as presenting 3 samples to a Lab and allowing the samples to be randomly allocated to a track. We know that a patient sample can go on a range of routes, but we are not calculating odds as to its path so rather than throwing dozens of samples per month at the sample handling module to try to ensure that there was a statistically reasonable chance to guarantee each 'box' gets assessed monthly, we are targeting each 'box' with just 3.

If you want to consolidate your EQA and you don't currently do all the possible analytes in our General Chemistry Scheme, so you might wish to switch on the rest; this will have no financial impact for you and might assist you in assuring your Trust and your patients of the overall quality of your service in these difficult times. If you don't currently subscribe, we would be happy to provide you with some free participation for a trial period if you thought that this would be helpful.

If it is concerns over specimen safety, then our samples are essentially no different to your routine samples. Many of them will have been in our freezer for some time and would be likely to predate the current Covid-19 outbreak. We are risk-assessing the specimens that we are dispatching and we are using the lowest risk where there are options.

In summary, in general terms, as an EQA provider for over 50 years, the UK NEQAS position is that EQA shouldn't be considered a luxury but is at the heart of a Laboratory's QA and QM strategy. Having worked from the Birmingham Quality Centre for 33 years, I would – as you would expect me to say – recommend that rigorous, regular EQA should always be performed. As an ISO17043:2010 Accredited EQA provider, we try to match pragmatism with science. Most of our Participant and our Advisory Groups advocate our monthly, three-specimen Scheme Design. Interestingly, a recent Participant survey from a few years' back at the end of 2017 gave a staggering 93% approval rate from 272 replies wished us to continue with a fortnightly distribution schedule. This reflects the through-put of these analytes in a typical Laboratory and the need for a more timely intervention in the case of a wayward analyte more than compensated for the high EQA sampling rate. That said, we are likely to implement a monthly service for UK NEQAS for Clinical Chemistry during this Covid-19 infection period. Like all of us in the NHS and beyond, we have to re-evaluate what we do.

Yours faithfully

Finlay MacKenzie

Finlay MacKenzie, Director Birmingham Quality