Congratulations of your recent stage 2 approval. We will now arrange your stage 3 assessment. The following document contains information on the administrative processes that are in place as well as the frequently asked questions that we have received regarding the Stage 3 assessment process and content, we hope that you will find this useful.

Stage 3 assessment process

Operational structure - Technical team

Section Head – Ben Courtney

- Senior Assessment Manager – Lead assessors and technical decision maker for team design and accreditation granting.
- Assessment Manager – Lead assessors who conduct QMS reviews on assessments

Operation structure – Administrative team

- Customer Service Manager – Elizabeth Kilbee-Johnson
- Team Leader – Le Tran
- Customer Liaison Officers – the staff who arrange the assessments

Visit Booking Process:

- Assessment Manager passes information over to the Customer Liaison Team detailing who is required for an assessment and for how long.
- The customer liaison officer will reach out to each provider to offer dates that they have arranged with the team.
- Once the dates have been agreed with the customer and the team the Customer Liaison Officer will issue an assessment confirmation and quotation.
- For remote assessment you will be sent a calendar invite with a link to a Microsoft Teams meeting, this is used for the assessment.
- The Assessment Manager will be in touch prior to the assessment to talk through the logistic of the day.
- If you have been issued a PAT, please ensured this is return to UKAS completed 5 working days prior to your assessment starting.

Close out meeting and Non conformality review:

- This will be done by a meeting or by document review. The lead assessor should arrange this with you at the end of the assessment or very soon afterwards
- Time allocated for these meeting or document review is chargeable time and you will be issued with a quotation.
- If a close out meeting date hasn't been prearranged the Customer Liaison Team will reach out to you to offer dates.
- For close out meeting a new Microsoft Teams link will be sent to you.
- For document reviews please email all correspondence to Medlabscustomerservice@ukas.com. The team will always send an acknowledge of documents received email once processed.

If you need information regarding your assessment and you are unable to contact the Assessment Manager please contact the Customer Liaison Team, they may be able to answer your query or will be able to escalate appropriately

- Medlabscustomerservice@ukas.com Please also quote your customer number in any email sent.

Frequently Asked Questions and Answers

Q: So providers need to have obtained a copy of the relevant standard for the activities they are applying for accreditation for?

A: You are required to have purchased a copy of the relevant standard – either ISO 15189 or ISO/IEC 17025. If you are applying for POCT then you will also need to have a copy of ISO 22870. You should have reviewed the requirements against your processes to ensure that you meet the requirements of the standard(s). If you wish to apply for POCT then you will need to apply for ISO 15189 and ISO 22870.

Q: Are there any guidelines for the costs involved with the stage 3 assessments – sampling, sampling plus POCT and or testing?

A: Yes, we have estimated the costs involved for each type of assessment and also for when there is more than 1 site involved. These costs can be found on our website here:

https://www.ukas.com/accreditation/about/accreditation-costs/covid-19-private-provider/

However, each case will be reviewed and assessed as required so these estimates are only a guide.

Q: What is the process for a Stage 3 sampling or sampling plus POCT assessment?

A: When you have been approved at stage 2 you will then move to stage 3 – the assessment phase of the process. You will now be allocated an Assessment Manager – the person who will lead your stage 3 assessment. We will contact you to discuss suitable dates and when these have been agreed we will confirm your assessment day(s) with you and send you a copy of the relevant PAT – either the PAT for sampling assessments or the PAT for sampling and POCT, a link to the SharePoint folder that has been set up for your assessments – this is where you should upload all documentation to support your assessment – as directed from the PAT. We will contact you to arrange the stage 3, you do not need to contact us.

Please upload this information at least 5 working days prior to your assessment so that the team can review it. Your Assessment Manager will contact you to discuss and confirm the arrangements for the assessment – timings etc. The assessment itself will start with an opening meeting around 9am, the assessment will continue throughout the day and end at around 5pm. If a longer assessment in required, then the length of the assessment will be as per the confirmation email. You will need to ensure that appropriate staff are available to work with us on the assessment, not all staff are required to be present at all times, unless you wish them to be. We will need to witness the sampling process and POCT process, the arrangements for this will be confirmed at the opening meeting. We will document the assessment as we go through the day and if any gaps are identified then we will raise a finding and agree an improvement action with you. This will be documented within the PAT which will be forwarded to you after the assessment. If any findings are raised, you will have four weeks to address them – the exact date for this will be discussed and agreed with you. The improvements actions will be reviewed with you – either at an additional teams or zoom meeting or by document review. Your Assessment Manager will confirm the approach with you If an additional assessment is required. you're Assessment Manager will also confirm this with you. An independent decision will be performed by a Decision Maker at UKAS and you

will be issued with an offer of accreditation later which must be signed and returned to UKAS Once all findings have been cleared, the offer letter returned and the assessment has been reviewed and approved by an independent Decision Maker at UKAS accreditation will be granted. The assessment of laboratories will generally be performed on site.

Q: Will all of the stage 3 assessments be performed remotely?

A: The assessment required for the sampling providers will be fairly straight forward and we believe that these will be able to be assessed remotely (via MS Teams or Zoom). For large complex laboratories we may need to visit and go on site, this will be dependent on what activities are actually being performed. Whilst we are confident in our skills to assess remotely there are circumstances where we have decided that an on-site assessment is necessary, such as the for the assessment of the Lighthouse laboratories and other large Covid testing laboratories last year during lockdown.

Q: What time do these assessments usually begin and how long will you require to see our sampling process as we need to organise our clinical appointments. Could you kindly give us an overview of what the day will look like please and what to expect? Could you do a run through of the Stage 3 assessment day. We have a date for ours. Have been sent the forms to complete, but not the agenda for the day? How long the day will be? Do we need the whole team involved to be available on the day? Could it be any longer than a day?

A: You will receive a copy of the PAT and your Assessment Manager will be in touch with you. The assessment will be 1 day in duration, it is likely to start at 9am and finish at approx. 5pm, your Assessment Manager will agree a time for the sampling assessment observation. We will try and work with you to arrange this at a suitable time. You will need to make sufficient staff available to guide us through the processes in place at your organisation.

Q: Post accreditation, what is the expectation with regards to changes? What changes must be submitted? What turnaround times for reviews are expected? And how long will it take to go from change notification to approval (accreditation)?

A: It will depend upon what the change is, so the key thing is that you inform us as soon as you start to plan the change so that we can work with you and advise you on the work that we will need to see to approve that change. If for example, you are a provider who is changing the laboratory that you use, or adding an additional laboratory to your process, that might be very straight forward, if that laboratory is already accredited. If you are a laboratory wanting to bring in a new test for your PCR then that would be a more comprehensive process for us to assess and accredit. The key is to notify us as soon as you start to plan these changes so we can advise you on what will be required and if a formal extension to scope will be required.

Q: We are a mobile provider of testing. how would that work for stage 3 visit?
Q: Does the stage 3 assessment have to be in person? We do mobile testing at client's offices or homes - so it would be tough to do this on client site

Both answered below:

A: From our perspective, it doesn't matter where you are, we will conduct the assessment remotely, using MS Teams or Zoom. What we would look at is that you have things in place, by submission of evidence in advance of the assessment and we would talk to you on the day of the assessment and we would look to witness what's actually happening in terms of sampling. It doesn't make any difference really where that would be. If you've got mobile sites, we would need to assess your general process for assessing the suitability of the site and meeting the requirements, which is completed prior to you visiting the site. We would work with you to ensure we can suitably assess this in a way that is as convenient as possible to you.

Stage 3 support

Q: How do providers get access to the eLearning PASS modules?

A: All organisations who are either working towards stage 2 approval or have been stage 2 approved should now have received information on how to enrol for the PASS modules. If you have not and would like to enrol please follow the links below:

- If you would like to enrol any users and you have not yet taken the survey, please provide the requested details here: https://www.surveymonkey.co.uk/r/62DNKQN - Please note that each requested user must have a unique email address for us to grant them access. A generic email cannot be used for more than one user.
- If you believe you have already enrolled but have not yet received an invite to the learning portal, please check your junk mail for notifications from notifications@learnupon.com
- If you have already enrolled but would like to enrol additional users, please reply to this email, completing the requested information included below my signature.
- If you have already enrolled but have lost the email or are not sure how to access the portal, please try logging in here: https://ukascommercialtraining.learnupon.com/

Q: How much guidance will be issued to help providers prior to stage 3? Will there be documents sent or webinars arranged?

A: You will all have had links to the PASS modules which takes you through the process in a step by step fashion and through the requirements that you will have to meet and it also talks about the assessment and how that will work including the provider assessment tool (PAT) which we will use to document your assessment as well. The PAT will be issued prior to the assessment with the assessment confirmation and you can input information into that. This will also provide you with guidance on the process and what we will be looking at. Weekly webinars - drop-in sessions are being held. The PASS modules are there to help you with that and should take you through that. If you have any queries or questions, please email the team at covid@ukas.com

Q: Is there an example of the PAT that can be shared?

A: Yes, the PAT is discussed and embedded into one of the PASS modules and a copy will be emailed out with your assessment confirmation letter for you to populate and return to us before your assessment takes place.

Q: Are the PASS eLearning modules optional or mandatory for stage 3 assessments, and are all staff required to complete them?

A: The PASS modules have been designed to support providers by explaining the processes that are place, breaking down the requirements and explaining what documentation is required – policies, procedures and records etc. It is not mandatory that the PASS modules are completed by the providers, however, it is very strongly recommended that they are.

Stage 3 assessment technical questions

Q: When applying for sample testing is it possible to add POCT LFT at a later time and what would be involved?

A: If you wish to add any additional testing or activities to your scope of accreditation then we have a process for that called an extension to scope. You would apply for that and we would assess it with to ascertain if the new activity meets the requirements of the standard in the normal way and when that has been completed and any findings cleared then the new activity/test would be added to your scope.

Q: Is there a separate accreditation process for Day 2 and Day 8 testing?

A: There is not a separate accreditation process for day 2 & day 8 testing, but there is a separate route, there is a separate approval process for this which can be found on the DHSC. We are requesting laboratories to complete a separate self-declaration for this. If you are a sampler working with ta laboratory performing this testing then you do not have to complete a self-declaration – that is the responsibility of the laboratory who declare on your behalf. As part of the self-declaration the laboratory completes, they include a list of the sampling providers that they are working with to DHSC and UKAS, and we check that those sampling providers are applicants of UKAS and working through the process. So it is a separate list, a separate process and only the laboratories have to self-declare.

Q: In preparation for TTR stage 3 validation compliance can you confirm if 150 clinical positive samples and 250 clinical negative samples are required to be swabbed directly from patients, i.e. patients swab themselves twice, then send one sample to the reference lab and one sample to the test lab, or can they be historically confirmed positive swabs that have been processed and stored in transport media?

A: Historically confirmed positive samples are fine to use for validation purposes.

Q: How can we ensure that reports are sent to the correct person, unique QR is used, along with barcodes and double check mechanisms with 2 member of staff – what else might be required here?

A: There is a clause in ISO 15189 – section 5.10 regarding validation of systems for reporting, so whether you are reporting by email, SMS or by post you are required to do some sort of testing to confirm that the reports are getting to the right people, and also that they are being received in the format in which they were sent out. This is sometimes done using dummy emails addresses and tested using those or asking a recipient for help in letting you know what has been received to ensure that that all is how it should be. If you are using an IT provider is that provider certified for data security and is this something you take into account when approving your suppliers in terms of validating the systems to ensure that they work correctly.

Q: Are there minimum requirements for the validation of reporting software?

A: Unfortunately, there is no black and white answer here, and the answer is "it depends" because it depends on the type of software in question. For example – if you are emailing PDFs out, this will require much less validation than if you are a laboratory with a large and complicated laboratory management system. It is then up to you to justify why your validation plan is sufficient and appropriate for the systems being validated and to assure yourselves, and UKAS that those systems are working correctly as planned.

Q: For sample providers wishing to do Day 2 and Day 8 swab sampling, do we need to submit again something in addition to general testing and test to release 5 day? We're awaiting the laboratory getting confirmation from the DHSC re authorisation for this, but what do we need to do. We have progressed to stage 3 for GT and TTR.

A: Regulations require that the laboratory submits the self-declaration on your behalf and that they take responsibility for that provision of the service so in terms of what you need to do it is minimal at this stage. When we get to the assessment, we will look at reporting but until that stage it is for the laboratory to take responsibility. Sampling providers will also need to ensure that they meet the regulations regarding that process.

Q: What is the procedure to add on a new laboratory on our application that we would like to work with as a sample taker?

A: If you want to add on an additional laboratory send a formal email to applications@ukas.com ensure that you include your UKAS reference number and project number that you have been provided with and state clearly which laboratory including the reference number you are intending to use and whether you are using them for general population testing and/or test to release (TTR). Ensure that if using a lab for TTR check that they meet their specifications.

Q: How can sample collectors show that laboratories used hold appropriate accreditation? Is the fact that they appear on the gov list of private COVID test providers sufficient?

A: If the lab is on the gov.uk list it is ok to use. If we have any concerns, we will come back to the provider.

Q: We are in the process of accreditation for 15189 sampling only, can we apply for extension for 22870 prior to completion of Stage 3. If we can what would be required for this application, do we use the same Gap Analysis doc and evidence as before or are there other forms.

A: Yes, you can add it on. Send a formal email to UKAS applications. Yes, you use the same gap analysis template, but it would probably be best if you do a separate gap analysis for POCT. Don't forget that all of ISO 15189:2012 applies apart from a small number of clauses that have additional POCT requirements so ensure the gap analysis is to both ISO 15189:2012 and ISO 22870:2016. In terms of the application form, you probably submitted the sample only application form the first time round so you will probably need to submit an additional/amended application to detail what POCT kits/methods you are using and to tick the fields to indicate you are seeking accreditation to ISO 15189:2012 and ISO 22870.

Q: In terms of having procedures in place to deal with reporting and resolving adverse incidents, how do we (as a sample collector) provide an idea of how these are dealt with in practice when there is a wide range of issues that could occur? Is it essentially just saying that we need to have someone who will investigate such issues?

A: You will need to have a documented procedure, i.e. a description of, step by step, how you would identify an adverse incident, what staff should do when one occurs, where, how and when do they record this, where, how and when do you /they record the investigation into the incident. How does this feed into the organisation governance system? How do you ensure that anything reportable to an external body is done and recorded? How do you ensure awareness and learning from incidents? How do you communicate resolution to the individuals involved? How do you trend incidents? These are just some of the points to consider when documenting your procedure for management of incidents.

Q: For sample collectors, clinicians performing swabbing for lateral flow testing what levels of EQA (External Quality Assurance) are required when an IQC (Internal Quality Control) programme is already in place.

A: For POCT EQA it is important to have an EQA mechanism in place as part of your overall quality assurance system. A number of different programmes/schemes are available, UKAS are not able to comment, or suggest any particular ones as we remain impartial, but we are aware of a number and that there is information available on these schemes on the internet. In terms of what is appropriate – all EQA (or PT) providers will have a number of distributions available each year, so you would need to discuss this with them to determine if their distributions meet your requirements. You will also need to consider who many distributions you would need to complete in order to demonstrate your own competency and performance (accuracy and precision) for the testing you perform. This would be performed in conjunction with your IQC mechanisms. If IQC is performed via a peer – you will therefore need to have clear information on the number and type of samples that are being used so that you have enough information to be able to complete the picture, for yourselves, on how your

testing/assays are performing and whether you are performing sufficient IQC and EQA testing to give you this information.

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There is information on the Gov.uk website on the Day 2 and Day 8 testing process.