Private Providers of Covid-19 testing
Frequently Asked Questions

Who needs to fill out the self-declaration form? What does end-to-end provider mean?

The organisation that customers approach to access the testing service (and whose name can appear on the gov.uk list for customers to contact to access the service) is responsible for completing the self-declaration form. It may be that this organisation runs the whole testing process or that various parts of the process are sub-contracted out to other organisations, in which case this will need to be documented in the self-declaration form. However, the customer facing, end-to-end provider will be the organisation responsible for filling in a self-declaration form and appearing on gov.uk

If the organisation is sub-contracting other organisations to carry out lab services or sample collection services, the contracted organisations will need to be applicants for UKAS accreditation and will need to share their registration number/accreditation number with the customer facing provider and progress through the staged accreditation approach. The sub-contracted organisations do not need to fill out the full self-declaration.

Are POCTs covered by UKAS accreditation?

Yes. Test services that provide POCTs, where samples are analysed by the test service provider/a sub-contracted organisation, must be UKAS accredited against ISO 15189 and ISO 22870.
If the POCT is taken at home, please see below.

Are home based tests covered by UKAS accreditation?

For home-based tests, where samples are taken by individuals and are then sent to a laboratory, the laboratory must be covered by UKAS accreditation. Laboratories need to be accredited to ISO 15189 or ISO/IEC 17025.

For home-based tests, where samples are taken by individuals and are then sent to a POCT provider to analyse, the provider must be covered by UKAS accreditation to ISO 15189 and ISO 22870.
For home-based tests that are sold by the provider, but the provider does not collect the sample or analyse the test – so the test is analysed at home (i.e. new LFD technologies), the provider that sells the tests does not require UKAS accreditation.

What about self-administered samples?

For self-administered samples that are collected by the individual undertaking the test and then sent to a laboratory for analysis, the laboratory must be covered by UKAS accreditation. Laboratories need to be accredited to ISO 15189 or ISO/IEC 17025.

For self-administered samples that are collected by the individual undertaking the test and then analysed by a POCT provider, the provider must be covered by UKAS accreditation to ISO 15189 and ISO 22870.
For self-administered samples that are 'self-analysed' - collected by the individual undertaking the test and analysed by the individual undertaking the test (e.g. using new LFD technologies) - the provider that sells the tests does not require UKAS accreditation.

What ISO standards are relevant to me?

If you will be providing services using lab-based tests, you will need to apply for UKAS accreditation to ISO 15189 or ISO/IEC 17025. If you foresee your organisation offering POCT in future, we recommend you opt for ISO 15189 for sampling so that POCT can be added at a future stage.
- If you are contracting sample collection you must use a UKAS accredited/applicant sample collection service registered/accredited to either ISO 15189 or ISO/IEC 17025.
- If you are contracting laboratory services you must use a UKAS accredited/applicant laboratory registered/accredited to either ISO 15189 or ISO/IEC 17025; and

If you will be providing Point of Care test services, you will need accreditation to ISO 22870 and ISO 15189.
- If you are contracting sample collection you must use a UKAS accredited/applicant sample collection service registered/accredited to ISO 15189
- If you are contracting laboratory services you must use a UKAS accredited/applicant laboratory registered/accredited to either ISO 15189 or ISO/IEC 17025

When applying to UKAS you can specify the activities you are undertaking that need to be accredited under ISO 15189 or ISO/IEC 17025. This means that you can apply to only carry out sampling activities. The UKAS forms will refer to the term "laboratory" but for the purposes of your application as a sample collection service please consider this to mean "provider of sample collection services". There are no barriers to applying for accreditation if you do not consider your business/service to fall under the definition of a "laboratory". UKAS will be reviewing the forms in due course but please use the current forms and contact UKAS if you have any queries at covid@ukas.com.

If sampling and testing for TTR (effective from 15/12/2020), can we operate whilst waiting for accreditation or do we have to wait for accreditation to be approved?

Once the 'end-to-end provider' has submitted the self-declaration form, UKAS will review it within 5-7 days. In order to ease the process for providers, we consider Stage 1 to be complete as soon as you/your contracted services have (1) applied to UKAS against the relevant ISO standards and (2) you have submitted your self-declaration form. At this point you have completed Stage 1 and can continue to operate your testing services.
However, you will only be added to the list of providers once you have completed UKAS Stage 1 and UKAS has reviewed and approved your self-declaration.

If we are offering a service but not swabbing or undertaking the tests, do we need to be accredited?

If you're not performing any of the lab or sampling activities then no, your service cannot be accredited. Your providers will need accreditation and DHSC will recognise your organisation as working with those other organisations.

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The UKAS staged process

UKAS and DHSC have launched an adapted three stage process for providers of Covid-19 test services. The stages are:
- Stage 1 UKAS Applicant
- Stage 2 UKAS Appraisal
- Stage 3 UKAS Accredited

Stage 1
1) Apply for UKAS accreditation against the relevant ISO standard for lab-based tests, either ISO 15189 or ISO/IEC 17025 or, for point of care testing, ISO 15189 and ISO 22870 https://www.ukas.com/services/accreditation-services/apply-for-accreditation/
   a. If you are NOT UKAS registered – the first step of the registration process is for you to apply to UKAS against the relevant ISO standard.
   b. If you are already UKAS registered for other activities – you need to apply to extend your scope to cover Covid-19 testing.
2) Once you have submitted your application to UKAS you can self-declare against the minimum standards on gov.uk. You can find the minimum standards for general testing here and for testing to release for international arrivals here.

You only need to apply for self-declaration if you are the organisation that customers approach to access the testing service aka the 'end-to-end provider' and whose name should appear on the gov.uk list for customers to contact to access the service. If you are the laboratory or sample collection service contracted to an 'end-to-end provider' you must apply for UKAS registration and share your registration number with the 'end-to-end provider' **as they will need your registration/accreditation number to complete the self-declaration form.**

Stage 1 is complete when the 'end-to-end' provider and any contracted services have applied for UKAS registration/change of scope or can show they already have UKAS accreditation for Covid-19 testing and the 'end-to-end' provider has submitted a self-declaration form.

In order to provide tests on the English market after 31st December, you will need to complete this stage. Before providing any tests for Test to Release, you will need to have completed this stage.
After completing Stage 1 of the UKAS process, you may be contacted by DHSC for further information, or you will be notified that your application was successful and, if you are the 'end-to-end provider' your service will be published on the list on gov.uk.
Please note: all organisations will need to complete (1) before the 'end-to-end provider' starts (2), as they will need to provide your UKAS accreditation number or your UKAS registration number/application reference to complete the self-declaration form.

Stage 2
Obtain UKAS appraisal against 13 key requirements. More information can be found on the UKAS website.
In order to continue to provide tests on the English market after 31st December 2020, you have until whichever is later of 31st January 2021 or 4 weeks after completing Stage 1 to complete Stage 2 Appraisal Status. If you are providing tests for Test to Release, you will need to complete Stage 2 by whichever is later of 18th January 2021 or 4 weeks after completing Stage 1.

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Stage 3

Obtain UKAS accreditation against the ISO standards that you have applied against.
In order to continue to provide tests on the English market, or for Test to Release, after 31st December 2020, you have until whichever is later of 30th June 2021 or 4 months after completing Stage 2 to complete your UKAS accreditation.

Will UKAS be doing site visits for these assessments, or remote assessments using videos/zoom calls?

This will vary depending on the organisation. UKAS is carrying out remote assessments at the moment, which are proving to be very effective. Ultimately it will depend on the services you deliver and what we deem as essential to witness. We are still able to go on-site if necessary.

Are both NHS labs and private providers being treated equally?

UKAS has responded to government requirements and we've done that by putting this staged process in place. This new process of application to accreditation is different from others because we know the pressure that providers are going to be under in order to achieve accredited by June. We understand that is a difficult ask and that's why we needed to introduce a new process. The assessment and resulting accreditation will be of the same rigour and value to the organisation,

How long will the staged process take?

Once the 'end-to-end provider' has submitted the self-declaration form, UKAS will review it within 5-7 days. In order to ease the process for providers, we consider Stage 1 to be complete as soon as you/your contracted services have (1) applied to UKAS against the relevant ISO standards and (2) you have submitted your self-declaration form. At this point, you have completed Stage 1.

However, you will only be added to the list of providers once you have completed UKAS Stage 1 and UKAS has reviewed and approved your self-declaration.

Once you have completed Stage 1 and gained Applicant status you have until whichever is later of 31st January 2021 or 4 weeks after completing Stage 1 to complete Stage 2 Appraisal Status.

Once you have completed Stage 2 and gained Appraisal Status, you have until whichever is later of 30th June 2021 or 4 months after completing Stage 2 to complete your UKAS accreditation.
Please be aware that these timeframes differ for Test to Release test providers.

How much will this cost?

The cost of the entire UKAS accreditation process will vary based on the size of your service.
The cost of the UKAS registration is a standard price of £1500 + VAT for all organisations. Subsequent assessments will then depend on the number of sites, the model of delivery and what UKAS deems critical to assess. Each customer will receive a formal estimate after they submit their documentation.

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How long will it take to gain Stage 1 Applicant status?

Once the 'end-to-end provider' has submitted their self-declaration form, UKAS will review it within 5-7 days. In order to ease the process for providers, we consider Stage 1 to be complete as soon as you/your contracted services have (1) applied to UKAS against the relevant ISO standards and the 'end-to-end provider' (2) has submitted their form. At this point Stage 1 has been met.

However, the 'end-to-end provider' will only be added to the list of providers once they have completed these two steps (Stage 1 Applicant Status) and UKAS has reviewed and approved the self-declaration.

Will UKAS be doing site visits for these assessments, or remote assessments using videos/zoom calls?

This will vary depending on the organisation. UKAS is carrying out remote assessments at the moment, which are proving to be very effective. Ultimately it will depend on the services you deliver and what we deem as essential to witness. We are still able to go on-site if necessary.

I made a mistake in my form, do I need to withdraw it?

If you, the 'end-to-end provider', have already submitted your self-declaration form but have now realised that you did not include a UKAS application number, please email PrivateProviderSelfDecQueries@dhsc.gov.uk to handle your changes.

If you have already submitted your self-declaration form but forgot to add in some information, please email PrivateProviderSelfDecQueries@dhsc.gov.uk to handle your changes.

We are continuing to work on the functionality of the self-declaration form and expect that it will soon be possible to edit forms that you have started filling in.

Do we need to report test results?

There is a statutory duty for test providers and laboratories to report positive, negative, void, and indeterminate SARS-CoV-2 test results to Public Health England (PHE). This includes results from both laboratory-based tests and point of care tests. Guidance for reporting test results can be found here.

Is PHE reporting required for POCT (e.g. antigen swab) testing?

Yes - because, as part of the self-declaration, DHSC have stated that whether it is point of care testing or lab-based testing - regardless of the type of test - they require that the test results are reported.

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Self-declaration

What are the most common problems at Stage 1?

The most common delay to self-declaration approval is the lack of a registration with UKAS. An application including the UKAS Application Form, UKAS Agreement, AC4 or AC6 form (AC4 for ISO/IEC17025 application; AC6 for ISO 15189 and ISO 22870 applications) and the application fee is required. You will receive formal acknowledgement of your application. This will be sufficient to meet the minimum standard requirements relating to accreditation application.

In addition, the MHRA have published Target Product Profiles (TPPs) for different types of test. This has been developed to help manufacturers design and deliver tests that are fit for purpose. The TPPs set out the scope of what the test should be used for (target use, target user and target settings). As a provider, you must declare that the test being used is in line with the published scope. Leaving this blank and not confirming that you are satisfied that a TPP has been met, or that you have verified the testing to meet requirements, will result in a delay to progressing the application.

Do we need a medical director and/or healthcare scientist?

We can confirm that the expectation is that test providers applying for UKAS accreditation have access to:
- clear clinical medical advice from a Chief Medical Officer/Medical Director - this is to ensure that there is clear accountability within your organisation for everything related to clinical and medical matters and that that person is registered with a regulatory body; and
- clear scientific advice from a healthcare scientist - this is to ensure that your organisation is proceeding with any COVID-19 related activities under the advice of a trained regulated scientist who has the relevant scientific and infectious sciences/virology expertise. This individual should be a regulated healthcare scientist who is registered with the Health and Care Professions Council or another relevantly trained person who can take the place of a regulated healthcare scientist for the purposes of accreditation (e.g. a Chief Pharmacist). UKAS have noted that it is not uncommon for this to be provided by an individual or individuals that are contracted to organisations for that specific purpose and not permanent members of staff.

It might be that your service sub-contracts laboratory services, in which case, the sub-contracted lab might be best placed to provide scientific advice and oversight. If this is the case, UKAS will assess your application on a case by case basis, so please provide UKAS with these details in the self-declaration form.

If you are a GP – please see the GP related queries.

If sampling and doing POCT e.g. lateral flow rapid antigen test, what is the requirement regarding having a healthcare scientist?

That's where it is important to introduce relevant scientific expertise. ISO 15189 and ISO 22870 ask you to use your expertise to look at your service provision to see what's needed and, if necessary, contract that in.

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Do I need to do a UKAS application before self-declaring?

If you are the 'end-to-end provider', you need to complete your UKAS application (and if you work with sub-contractors for lab services or sample collection services, they also need to do this) before you can complete the self-declaration form.

This is because you will need to be able to provide the relevant UKAS accreditation numbers or UKAS registration numbers in order to evidence that you meet the following minimum standards:

- Samples shall be taken by a provider meeting or working towards ISO standard ISO 15189 or ISO/IEC 17025
- For PCR lab-based testing: providers shall be or use a UKAS accredited lab or applicant laboratory to either ISO 15189 (Medical Laboratories – requirements for quality and competence) or ISO/IEC 17025 (general requirements for the competence of testing and calibration laboratories)
- For point-of-care testing: providers need to meet ISO standards ISO 15189 and ISO 22870 'point-of-care testing (POCT) – requirements for quality and competence'. Samples shall be processed by a UKAS accredited or applicant provider.

What is the requirement for accreditation for sample collection?

Your sample collection organisation needs to have submitted an application to UKAS against the relevant ISO standards. You, the 'end-to-end provider', need to complete your UKAS application (and if you work with sub-contractors for lab services or sample collection services, they also need to do this) before you can complete the self-declaration form. This is because you will need to be able to provide the relevant UKAS accreditation numbers or UKAS registration numbers in order to evidence that you meet the minimum standards.

If your organisation will be providing sample collection services, without a sub-contracted organisation, you need to extend the scope of your UKAS accreditation.

- If you are offering the sample collection as part of your overall testing process for laboratory-based testing, you must be registered/accredited to either ISO 15189 or ISO/IEC 17025.
- If you are contracting sample collection you must use a UKAS accredited/applicant sample collection service registered/accredited to either ISO 15189 or ISO/IEC 17025.
- If you will be offering the sample collection as part of your overall testing process for Point of Care test services, you will need accreditation to ISO 22870 and ISO 15189.
- If you are contracting sample collection for point of care tests you must use a UKAS accredited/applicant sample collection service registered/accredited to ISO 15189.

If you, the 'end-to-end provider', are contracting sample collection services, that service does not however need to fill out the self-declaration form on gov.uk as they are offering these services as part of your testing, and so only your company, as the 'end-to-end provider', will appear on the list.

When applying to UKAS you can specify the activities you are undertaking that need to be accredited under ISO 15189 or ISO/IEC 17025. This means that if you sub-contract testing to a laboratory service, you can apply to only carry out sampling activities. The UKAS forms will refer to the term "laboratory" but for the purposes of your application as a sample collection service please consider this to mean "provider as of sample collection services". There are no barriers to applying for accreditation if you do not consider your business/service to fall under the definition of a "laboratory". UKAS will be reviewing the forms in due course but please use the current forms and contact UKAS if you have any queries at covid@ukas.com.

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Private GPs who are undertaking private testing services

Do Private GPs need to self-declare against the minimum standards? Do Private GPs need to complete the self-declaration form?

The organisation that customers approach to access the testing service and whose name should appear on the gov.uk list for customers to contact to access the service, is responsible for completing the self-declaration form. This organisation is under a legal duty to be on their journey to UKAS accreditation, in order to provide tests for Test to Release from 15th December or for general testing after 31st December. This organisation is referred to as the 'end-to-end provider' as they are the organisation offering the test service to the customer. If a Private GP is the organisation that customers approach to access the testing service, they are the 'end-to-end provider' whether they conduct the whole test process or if they contract various parts of the process to other organisations, in which case the contracted organisations will need to be documented in the self-declaration form. However, the customer facing provider will be the organisation responsible for filling in a self-declaration form and appearing on gov.uk.

Which ISO standards are relevant?

We know that a number of Private GPs are collecting samples and (a) sending them to laboratories for analysis or (b) analysing them on-site as point of care tests. This represents two different models:
    (a) lab-based testing, with GPs conducting sample collection and sub-contracted lab services; and
    (b) point of care testing, where GPs collect samples and analyse tests

Private GPs carrying out the sample collection for laboratory based tests, using a sub-contracted laboratory's services, **will need to apply for UKAS accreditation to ISO 15189 or ISO/IEC 17025 for sampling and will need to ensure that they use a UKAS accredited/applicant laboratory to either ISO 15189 or ISO/IEC 17025.**

If you are offering test services and collecting samples and analysing them for a point of care tests, then **you will need to apply for UKAS accreditation to ISO 22870 and ISO 15189.**

If you are the organisation offering the test service to customers, you will need to fill in the self-declaration form – including details of UKAS applications by sub-contracted labs/other sample collection organisations that you work with. The form has the functionality for referencing multiple labs, as required.

If you are not the 'end-to-end provider' that offers the test service, but you are contracted for sample collection for that service, then you will need to apply for UKAS accreditation and send your application details to the 'end-to-end provider' that you work with (the UKAS accreditation you will need is ISO 15189 or ISO/IEC 17025 for lab-based testing, or ISO 15189 and ISO 22870 for point of care testing).

We need UKAS accreditation for ISO 15189 for sample collection, but we aren't a medical laboratory?

When applying to UKAS you can specify the activities you are undertaking that need to be accredited under ISO 15189 or ISO/IEC 17025. This means that if you sub-contract testing to a laboratory service, you can apply to only carry out sampling activities. The UKAS forms will refer to the term "laboratory" but for the purposes of your application as a sample collection service please consider this to mean "provider of sample collection services". There are no barriers to applying for accreditation if you do not consider your business/service to fall under the definition of a "laboratory". UKAS will be reviewing the forms in due course but please use the current forms and contact UKAS if you have any queries at covid@ukas.com.

Do GP services need healthcare scientists?

The minimum standard is a requirement of a clinical or medical director or equivalent and healthcare scientist.

The expectation is that test providers applying for UKAS accreditation have access to:

- **clear clinical medical advice** from a Chief Medical Officer/Medical Director to ensure that there is clear accountability within your organisation for everything related to clinical and medical matters and that that person is registered with a regulatory body; **and**
- **clear scientific advice** from a healthcare scientist to ensure that your organisation is proceeding with any COVID-19 related activities under the advice of a trained regulated scientist who has the relevant scientific and infectious sciences/virology expertise. This individual should be a regulated healthcare scientist who is registered with the Health and Care Professions Council or <u>another relevantly trained person</u> who can take the place of a regulated healthcare scientist for the purposes of accreditation (e.g. a Chief Pharmacist). Access to this advice and oversight is necessary in order to gain UKAS accreditation.

UKAS have noted that it is not uncommon for this to be provided by an individual or individuals that are contracted to the organisation for that specific purpose.

It might be that your service sub-contracts laboratory services, in which case, the sub-contracted lab might be best placed to provide scientific advice and oversight. If this is the case, UKAS will assess your application on a case by case basis, so please provide UKAS with these details in the self-declaration form.

Why do GPs need UKAS accreditation if we are already registered with the CQC?

This policy has been developed between CQC, UKAS, and the Department of Health and Social Care and we appreciate that some GPs are concerned about this being a regulatory burden on top of CQC registration that is required for other purposes.

The Government believes it is absolutely vital to bring in this scheme to provide public confidence in the excellent testing services that you provide and ensuring an agile regulatory environment for test providers. Previous legislation meant that some COVID-19 test providers were in scope and some are not. We need to ensure that customers are able to recognise one gold-standard for the services they procure.

In the past, while some test service providers may have been registered with CQC, they would also have to have UKAS accreditation, as some aspects of the test service (e.g. validation and calibration of testing) requires laboratory accreditation. CQC regulations focus on the quality and safety of the service being delivered. This approach will simplify regulations, creating one accreditation scheme for the whole end-to-end service.

We know private GPs might be registered with CQC for other purposes, however, if you wish to provide COVID-19 test services, you will need to comply with this legislative change, to simplify the testing landscape and, ultimately, provide confidence for customers.

If we are certified to ISO 9001, how much of information would be common for 15189?

Quite a lot of the management system requirements would be common to ISO 15189 and ISO/IEC 17025. Having certification will provide you with a good foundation, but it will be the technical side of the delivery that you'll need to consider for accreditation.

Where can we find more information on this?

Details of the UKAS accreditation scheme for Covid-19 test providers can be found here.

The UKAS application form can be found here.

There are two sets of minimum standards:

1. Minimum standards of general private test providers can be found here.

2. Minimum standards for private test providers providing tests for Test to Release for International Arrivals can be found here.

The form to self-declare against the relevant minimum standards can be found here. Please contact PrivateProviderSelfDecQueries@dhsc.gov.uk if you have any further questions.
Requirements for UKAS appraisal can be found here and full details of UKAS accreditation can be found here.

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