



Department  
of Health &  
Social Care

# **SERVICE SPECIFICATION**

## **DIGITAL NHS HEALTH CHECK PRIVATE BETA PHASE: FULLY MANAGED CHOLESTEROL and HbA1c SELF-SAMPLING SUPPLIER**

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## GLOSSARY OF KEY TERMS

<b>Contract</b>	means the contractual agreement entered into between the Department and the Supplier for delivery of the Goods and/or Services;
<b>Extension</b>	such period or periods beyond which the initial term of the contract may be;
<b>(The) Department</b>	means the Department of Health and Social Care.
<b>Goods and/or Services</b>	means the requirements of the Department for the Goods and/or Services from time to time as detailed in this document.
<b>Self-sampling</b>	Self-sampling involves the user collecting their own sample and sending it to a laboratory for testing and analysis. The user does not perform the test or interpret their own result.
<b>Service</b>	<b>Cholesterol and HbA1c</b> Self-sampling Service provided by the Supplier to the Department of Health and Social Care as set out in the Agreement but subject to any variations agreed by the Department of Health and Social Care and the Supplier
<b>Service user</b>	or plural, means the recipient(s) of the Service. These are individuals who are participating in the digital NHS Health Check
<b>Supplier</b>	means the Supplier appointed following this procurement process to provide the Goods and/or Services
<b>Tender</b>	means the Tender submitted by the Supplier to the Department of Health and Social Care
<b>Tenderer</b>	means an organisation that submits a completed Tender in response to this Invitation to Tender document

# 1. Executive Summary

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## 1.1 Overview

The NHS Health Check, established in 2009, is a key part of the CVD prevention pathway. The programme. Adults aged 40 – 74 years, who do not have an existing diagnosis of CVD, are invited for a free check every 5 years, during which top risk factors for CVD are assessed to calculate a person's CVD risk.

The Department of Health & Social Care (DHSC) is developing a digital version of the NHS Health Check. The vision for the digital NHS Health Check is to increase the flexibility and reach of the NHS Health Check through the creation of an innovative, accessible national digital service, delivered alongside the local face-to-face service, that helps people understand and take action on their cardiovascular health.

The intention is that the digital check can be self-completed independently by eligible people which will not only improve accessibility for users but also free up primary care appointments

A critical requirement of the NHS Health Check is the capacity to collect blood samples and analyse them for cholesterol and, where appropriate, blood glucose (HbA1c or fasting plasma glucose) among eligible participants in line with [programme standards](#). For the digital NHS Health Check cholesterol and HbA1C will be self-sampled at a user's home and the product sent to an offsite laboratory for analysis.

## 1.2 Aim

The aim of this service is to measure cholesterol and where required HbA1c via a self-sampling capillary blood test to enable eligible people to self-complete a digital NHS Health Check at home.

## 1.3 Summary of services

The Department of Health and Social Care will appoint a competent supplier to facilitate the delivery of end-to-end self-blood sampling through the digital NHS Health Check platform during the private Beta testing phase of the new digital NHS Health Check.

This service will be provided free of charge to eligible individual service users who have been invited to participate in the digital NHS Health Check private Beta phase by their local provider. The cost of the blood sampling element of the digital NHS Health Check for the private Beta phase will be met by the Department of Health and Social Care .

To ensure successful implementation, it is essential to recognise that the appointed supplier will need to collaborate with various stakeholders at national and , regional level, as well as local commissioners and providers. This collaborative effort is necessary to support the delivery of different elements within the digital NHS Health Check clinical pathway during the private Beta phase.

Integration with the NHS Health Check will be an essential aspect of the service.

Upon ordering a self-sampling kit(s) through the digital NHS Health Check platform, the supplier assumes the responsibility of providing service users with comprehensive information and guidance. This ensures that individuals are able to complete and return their self-sampling kits safely and in accordance with the manufacturer's instructions. To

facilitate this, all self-sampling test kits will include easy-to-read instructions, both in printed format and supplemented with links to videos or other media. By providing a range of instructional resources, the supplier is committed to addressing the diverse needs and preferences of service users participating in the private Beta phase of the digital NHS Health Check, ensuring a personalised and inclusive experience for all individuals involved.

## 2. Background

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### 2.1 Cardiovascular disease (CVD)

CVD is the second biggest killer in England. It affects around 6.4 million people, is the largest contributor to disability adjusted life years and accounts for around a quarter of the life expectancy gap between the richest and poorest in England.

### 2.2 NHS Health Check

The NHS Health Check is a key part of the CVD prevention pathway. The programme, established in 2009, aims to prevent heart disease, stroke, diabetes and kidney disease, and some types of dementia. Since 2013, local authorities in England have been legally responsible for commissioning the NHS Health Check programme as set out in the [Local Authorities Functions Regulations](#). The Government's public health grant to local authorities highlights provision of the NHS Health Check as a prescribed function, with general practice most commonly commissioned by local authorities to provide the service.

The regulations require adults aged 40 – 74 years, who do not have an existing diagnosis of CVD, to be invited for a free check every 5 years. During an NHS Health Check, the top risk factors for CVD are assessed and these are blood pressure, cholesterol, physical activity, smoking, alcohol consumption and BMI. Where required, blood sugar is also assessed in some people that are at an increased risk of type 2 diabetes. This information is then used to calculate a person's CVD risk.

As part of an NHS Health Check, all eligible individuals are made aware of their results, which are recorded in their medical record, and are supported to consider behavioural changes that will reduce their chance of heart attack or stroke within the next 10 years. All attendees are also made aware that the risk factors that are 'good for the heart, are good for the head', raising awareness of the risk factors for dementia. Additionally, attendees over 65 years are also told about the signs and symptoms of dementia and signposted to memory services.. Where appropriate, individuals are also supported to access further clinical diagnostic tests and drug treatment, for example diagnosing and treating high blood pressure (hypertension).

Since the current programme began in 2013, the overall national uptake of the NHS Health Check has never exceeded 50%. Consequently, the programme is not contributing as much as it could to reducing premature CVD mortality, and morbidity as a result of conditions including high blood pressure (hypertension), heart disease, stroke, type 2 diabetes, kidney disease and some types of dementia.

Data on the current levels of NHS Health Check activity can be found on Fingertips.

The majority of checks are conducted in GP surgeries. Currently 89% (124) of LAs reported that general practice delivered at least 3 quarters of the checks in their areas.

### 2.3 Digital NHS Health Check

The Department of Health & Social Care (DHSC) is developing a digital version of the NHS Health Check. The vision for the digital NHS Health Check is to increase the flexibility and reach of the NHS Health Check through the creation of an innovative, accessible national digital service, delivered alongside the local face-to-face service, that helps people understand and take action on their cardiovascular health.

The aim is that the digital NHS Health Check will offer participants the same assessment, as set out in legislation, through an additional, flexible mode of delivery. By capitalising on digital engagement during the pandemic, we want to improve and increase participation and reduce variation between areas by enabling people to self-check at home or to complete online with the support of friends and family, carers, community based health care professionals or volunteers. The check will empower users to take action to improve their health independently, link to national services, and enable general practice to initiate clinical care where appropriate.

The existing [legal requirements](#) for the NHS Health Check cover the following elements:

- Identify eligible population
- Invite eligible individuals
- Questionnaires and biometrics, including cholesterol and blood glucose (HbA1c) if required
- Communicate results to service users and their general practitioner
- Provide personalised advice on actions people can take to reduce their risk of CVD
- Refer people for clinical follow up and to prevention services

The intention is that the digital check can be self-completed independently by eligible people which will not only improve accessibility for users but also free up primary care appointments..

Our ultimate aim is to develop a digital service that, in combination with the face-to-face service, can help to transform the way users engage with, and providers deliver a NHS Health Check..

#### *Current status of the digital NHS Health Check*

Following successful Discovery and Alpha phases, DHSC is now in the private Beta phase, where the digital platform will be built and commence testing with a small number of service users within three selected local authority areas.

This next phase will help to refine the digital service, validate assumptions and inform the best approach for wider rollout.

## **2.4 Cholesterol and HbA1c self-sampling**

A critical requirement of the NHS Health Check is the capacity to collect blood samples and analyse them for cholesterol and, where appropriate, blood glucose (HbA1c or fasting plasma glucose) among eligible participants in line with [programme standards](#). This information, combined with demographic and behavioural information, height, weight and blood pressure for the participant, is essential to calculate the individual's 10-year risk of CVD and complete the NHS Health Check.

Currently, most NHS Health Checks are delivered by a healthcare professional with access to point-of-care testing devices that can analyse cholesterol and blood glucose (HbA1c or fasting plasma glucose) samples during an NHS Health Check appointment, or via venous blood sample that is sent to a laboratory for testing.

For the digital NHS Health Check cholesterol and HbA1C will be self-sampled at a user's home and the product sent to an offsite laboratory for analysis.

### 3. The service aims and objectives (general)

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#### 3.1 Aims and objectives of service

The aim of this service is to measure cholesterol and where required HbA1c via a self-sampling capillary blood test to enable eligible people to self-complete a digital NHS Health Check at home.

Key points:

- Cholesterol must be measured as the ratio of total serum cholesterol to high density lipoprotein cholesterol;
- A fasting sample should not be required for either cholesterol or HbA1c testing.

#### 3.2 Key service outcomes

The supplier will contribute to the following outcomes to support DHSC to deliver the private Beta phase of the digital NHS Health Check:

- Direct outcomes:
  - Provide service users with the end-to-end cholesterol and where required HbA1c self-sampling test service required to complete a digital NHS Health Check in the private Beta phase.
  - Interface with the central digital NHS Health Check platform to receive, process, distribute, return, analyse service user self-sampling test kit samples.
- Indirect outcomes:
  - Allow for the completion of a digital NHS Health Check

### 4. The service requirements (functions)

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The service is characterised by the following requirements:

#### 4.1 *Self-sample test ordering*

The supplier will be responsible for providing, hosting, managing and maintaining a secure and API interface to receive and process orders of cholesterol and where required HbA1c self-sampling kits from the digital NHS Health Check service, including a mechanism to order replacement kits. An example API specification has been provided (DRAFT appendix B HomeOrdering) that outlines the expected request body with mandatory fields to satisfy the requirements of the programmes self-sampling kit orders.

##### 4.1.4 Access

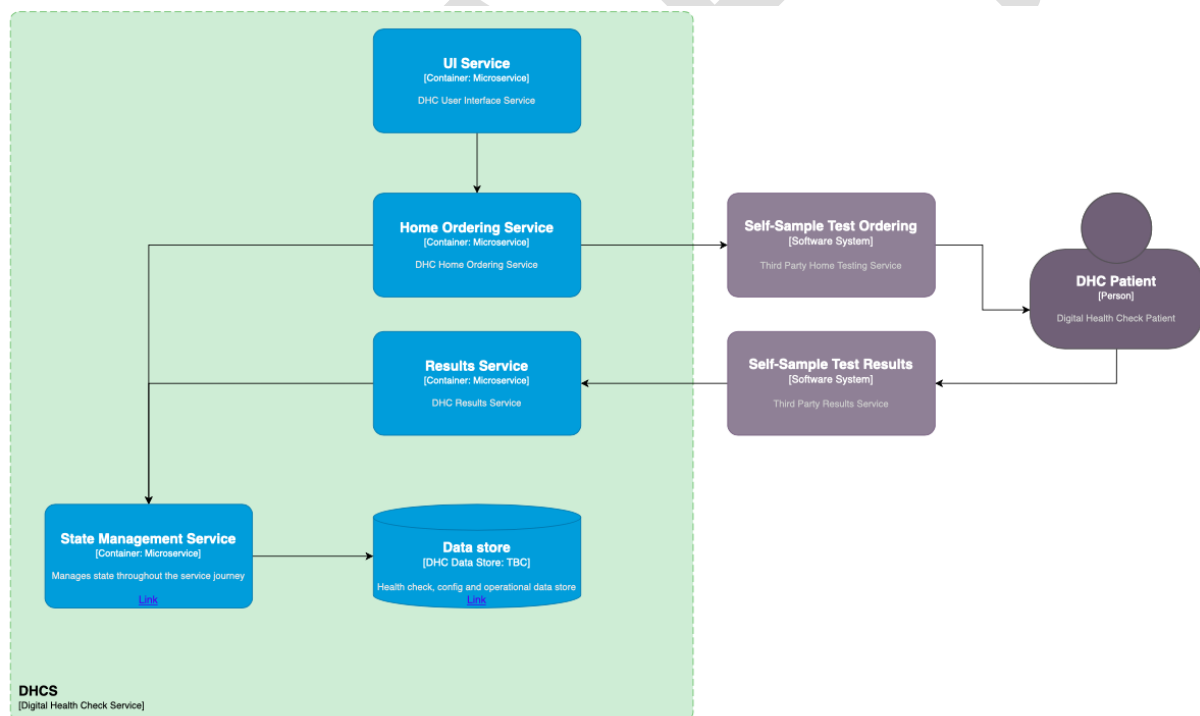
The technical interface must:

- Be a secure Restful API interface to receive kit orders from the digital NHS Health Check service.
- Have a mechanism to order a replacement kit(s) if required.

- If required, have the ability to link replacement kits back to the digital NHS Health Check platform, and provide an update to the digital NHS Health Check platform that a replacement order has been made via a Restful API.
- Provide the results, including flagging abnormal results, to the digital NHS Health Check platform via a Restful API for processing in line with programme standards. The digital platform will provide the result to the participant and their clinician, as outlined in legislation. All results (cholesterol & HbA1c) to be presented in mmol/L to align with National Institute of Health and Care Excellent guidelines.
- Be accessible 24 hours a day, 7 days a week with the exception of planned downtime for maintenance. Any periods of downtime should be planned with the digital NHS health check programme in advance, kept to a reasonable minimum (which should not be between 9-5pm) and a suitable message should be displayed to service users visiting the site during this period.
- Be able to accept orders from service users 24 hours a day, 365 days a year (with the exception of planned maintenance time).

### Technical interfaces

The following diagram provides a simplified view of the logical architecture and the two technical interface requirements:



#### 4.1.5 General data protection and security

Adhere to [National Cyber Security Centre \(NCSC\) Secure Design Principles](#) and [Protecting bulk personal data](#) principles:

- Comply with security standards at all times and should be registered with the Information Customers' Office (ICO).



- Comply with the UK General Data Protection Regulation 2018.
- Must assure and inform service users of their privacy and confidentiality where sharing of data happens outside of the digital NHS Health Check Service i.e. sharing with Lab (with DHSC to clear lines).
- Comply with the Information Standard, NHS England. [NHS England » Accessible Information Standard](#).

Provide relevant data for monitoring and evaluation purposes including KPIs outlined in section 18.

#### *Digital NHS Health Check results service*

The supplier will be required to integrate with the digital NHS health checks results API to send results back to the digital platform. All results (cholesterol & HbA1c) to be presented in mmol/L to align with [National Institute of Health and Care Excellence](#). A draft version of the results service API specification has been included in DRAFT appendix C ResultsService Please note, that this is not the final published version and is subject to change, however, it provides suitable information on how this service will function.

## **4.2 Requirements for the fulfilment of kit orders**

Coordination and management functions of the service (including dispatch of kits) should be delivered, as a minimum, during business operating hours 9am-5pm (GMT) Monday to Friday.

The end-to-end service must be available for use on the UK market currently (i.e., it has passed all necessary approvals and can be used with the intended groups and for the intended purpose).

The supplier is responsible for meeting the following requirements:

### *4.2.1 Online ordering of cholesterol and HbA1c self-sampling kits*

- Delivery of a sampling kit to the service users' preferred address (within the UK) which may, given the option, differ from their place of residence, in discrete and unbranded packaging. Fulfilment of cholesterol and where required HbA1c self-sampling kit orders free of charge to the service user.
- Supply of self-sampling kits containing: in-date consumables for capillary sampling; easy-to-read and comprehend sampling instructions in accessible formats (produced to reflect the diversity of service users and meeting the requirements set out in [Understanding WCAG 2.2 - Service Manual - GOV.UK \(www.gov.uk\)](#)); prepaid postage return envelope & suitable transport packaging according to packing instruction (PI) 650 for Category B UN 3373, diagnostic and clinical specimens containing biological and infectious substances.<sup>1</sup>
- Ability to manage stock of kits and demonstrate resilience and business continuity provisions to ensure orders are not rejected in the event of a temporary stock issue.
- Manage/have a mechanism for ordering replacement kits for those that are broken, spoiled or do not arrive within agreed timeframes.

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<sup>1</sup> Department for Transport. Guidance. Packaging and transport requirements for patient samples – UN3373. March 2020.

#### 4.2.2 Cholesterol and HbA1c self-sampling kits:

Must be licensed for self-sampling and be compliant with medical device regulations where applicable (the Medical Devices Regulations 2002, and general product safety regulations 2005) which includes UKCA or CE marking as applicable. The supplier should have a quality management system in place.

- Must contain easy-to-read and comprehensive instructions for sample collection and packing. This should include accessible printed instructions, supported with links to videos or other media (produced to reflect the diversity of service users)
- The lab must work with DHSC to determine the appropriate presentation of results
- Demonstrate evidence of low failure rates due to poor specimen collection or insufficient specimen. Provide information on sample void rates, including reason testing unable to be performed
- The self-sampling kits must require a maximum sample size of 600µl per test
- Must make provision for user support, such as telephone or email advice lines, to advise on self-sampling device usage.
- Supply evidence of user feedback on sample collection procedure to-date, and provide ongoing channel for users to supply feedback.

#### 4.2.3 Requirements of storage, packaging and transportation

- Must have the capability and capacity to store and distribute the appropriate kit/s required for cholesterol and HbA1c self-sampling to eligible individuals in line with service agreements.
- Suitable storage and transport conditions are met to ensure kit integrity and stability of sample. Must provide supporting quality documentation/medical laboratory validation of sample stability.

All packaging must conform with UN3373 packing instruction 650.<sup>2</sup>

The packing and contents of the kit should, as much as practical, use recycled materials and be recyclable.

- Kit packages must be posted first class and fit through a standard letterbox.
- Return packing must also be provided which will include the relevant pre-postal costs for the samples to be returned to the laboratory. Personal information must not be apparent and must not be identifiable from the packing design

##### *(a) Requirements of pathology (medical laboratory service)*

The supplier is responsible for providing, or sub-contracting, accredited pathology services in order to deliver the self-sampling service. The pathology services must be fit for purpose on the day the self-sampling service is launched.

The supplier must put service level agreements in place detailing turnaround times for sample processing and results reporting, across the end-to-end service.

Pathology laboratory services must meet the following requirements:

- Have capability to perform sample processing, testing, and result analysis on specimens for lipids and HbA1c, with capacity to cope with surges in demand.

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<sup>2</sup> Department for Transport. Guidance. Packaging and transport requirements for patient samples – UN3373. March 2020.

- Be UKAS accredited to ISO 15189 and able to demonstrate relevant scope on UKAS accreditation schedules (e.g. lipid & HbA1c testing included in detail of accreditation). Able to supply supporting procedure-specific and quality management documentation.
- Have current registration with the Care Quality Commission (CQC).
- Relevant tests must have been validated by the medical laboratory against gold-standard (venous blood) laboratory methods for lipids & HbA1c testing and have good accuracy. Must be able to provide strong supporting documentation demonstrating performance of the test (e.g. precision studies demonstrating acceptable coefficient of variation) where the specimen has been collected using the self-sampling devices to be supplied.
- For HbA1c - Tests must use a method which will detect common haemoglobin variants. The supplier must demonstrate how method accounts for test interferences for all testing

#### 4.2.4 *The provider is also responsible for*

- developing and adopting business continuity plans in the event that the laboratory is unable to provide contracted service.
- quality assuring the whole end to end service including choosing reputable suppliers and evidencing pre and post analytical elements of the service.
- registration with the Care Quality Commission (CQC) for provision of the entire Service and adhere to its incidence reporting policy.
- Incident reporting to MHRA within the regulatory guidelines ([Medical devices: guidance for manufacturers on vigilance – GOV.UK \(www.gov.uk\)](https://www.gov.uk/guidance/medical-devices-guidance-for-manufacturers-on-vigilance)).

## 5. Management information

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The supplier is also required to provide DHSC with management information including for the purpose of monitoring spend and for invoicing.

The management information required includes (but is not limited to):

- Number of service users ordering a cholesterol self-sampling kit and total number of kit orders.
- Number of cholesterol self-sampling kits distributed.
- Number of service users receiving a cholesterol self-sampling kit and total number of kits received.
- Number of service users returning a cholesterol self-sampling kit and total number of kits returned.
- Number of service users receiving a valid cholesterol test result and total number of valid results received.
- Number of cholesterol specimens not viable for processing at laboratory and reasons why and total number of invalid test specimens by reason.
- Number of service users requiring a replacement cholesterol self-sampling kit, and reasons why and total number of replacement kits sent by reason.
- Number of service users ordering a HbA1c self-sampling kit and total number of kit orders.
- Number of HbA1c self-sampling kits distributed.

- Number of service users receiving a HbA1c self-sampling kit and total number of kits received.
- Number of service users returning a HbA1c self-sampling kit and total number of kits returned.
- Number of service users receiving a valid HbA1c test result and total number of valid results received.
- Number of HbA1c specimens not viable for processing at laboratory and reasons why and total number of invalid test specimens by reason.
- Number of service users requiring a replacement HbA1c self-sampling kit, and reasons why and total number of replacement kits sent by reason.
- Turnaround times including:
  - Kit order to dispatch
  - Kit dispatch to sample return
  - Receipt of returned sample to analysing samples
  - Analysing samples to result reporting
- Available data on service users seeking further information and support to complete samples.
- Complaint rates and types from service users.
- Adverse event reports, in line with medical device certification requirements.
- Documentation of numbers of rejected samples and reasons for rejection (i.e. samples received but not tested).

The provider will also prepare and share anonymised, aggregated datasets (split by local authority area by GP address) with the Department of Health and Social Care on a monthly basis outlining the information above. This will be provided by the 15<sup>th</sup> of the month following that being reported on.

The service will be delivered in accordance with the quality outcomes indicators stipulated in this specification.

## 6. Population covered

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For the purposes of private Beta the population covered will be eligible population who are invited to and choose to take up a digital NHS Health Check within the local authority areas (**TO BE CONFIRMED**). However postal addresses may fall outside of these local authority areas but must be within the UK.

The service will operate at no expense to the service user.

## 7. Dependencies and interdependencies

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The supplier is expected to actively participate in evaluation activities for the private Beta Phase of the digital NHS Health Check where applicable.

## 8. Applicable service standards

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The service is to be underpinned by the following national standards and guidelines:

- [Local Authorities Functions Regulations 2013](#)
- [NHS Health Check Best Practice Guidance](#)

- [ISO Standards 15189 and 13485](#)
- [Medical device regulations 2002](#)
- [\(basically anything we have already mentioned above?\)](#)

The supplier will be required to demonstrate that they have a named lead, together with systems, processes and plans to ensure sound clinical governance. These systems, processes and plans should be in line with and adhere to NHS Clinical Governance Frameworks.

## 9. Data requirements

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### 9.1 Security

The supplier shall deliver the service in accordance with the HMG Security Policy Framework.

<https://www.gov.uk/government/publications/security-policy-framework>

The supplier shall have a Cyber Essentials Scheme Basic Certificate or equivalent at point of submitting their bid. Cyber Essential Scheme requirements can be located at:

[https://www.ncsc.gov.uk/cyberessentials/overview.](https://www.ncsc.gov.uk/cyberessentials/overview)

The supplier shall ensure that DHSC and service users' information and data is secured in a manner that complies with the Government Security Classification Policy rating of OFFICIAL-SENSITIVE.

[May-2018\\_Government-Security-Classifications-2.pdf \(publishing.service.gov.uk\)](#)

The supplier shall ensure that the Government Security Classification Policy rating is also applied when information and data is transmitted across all applicable networks and/or in line with the DHSC's requirements.

The supplier shall, where required, have the capability to employ encryption to information / data which shall be sent across a network or extracted by electronic means. The supplier shall ensure that the level of encryption complies in full with the Government Security Classification Policy rating of OFFICIAL-SENSITIVE and/or in line with the buyers' requirements.

The supplier shall ensure that any suspected or actual security breaches are reported to DHSC's representative immediately and depending on the impact of the breach, shall be included in monthly performance reporting to DHSC.

The supplier shall comply with all relevant legislation, organisational and cross Government policy and guidelines in relation to data and asset security.

### 9.2 Data processing

The supplier should have robust procedures in place for identifying, assessing, and reporting any personal data breaches (while complying with regulations). The supplier should have appropriate privacy notices in place to ensure that all individuals whose personal information you will process in the delivery of the service are informed of why it is needed, how it is used, what their rights are, and who the information is disclosed to.

### 9.3 Standards

The supplier shall provide secure solutions that comply with any restrictions or requirements arising out of DHSC's security policies. This shall include, but not be limited to:

Cyber Essentials Scheme Basic Certificate; or

or

ISO 27001 Information Security Management.

DHSC may require the supplier to undertake check assurance with a National Cyber Security Centre (NCSC) approved provider, this will be specified by buyers at call off stage. Further information on NCSC penetration testing can be found at:

<https://www.ncsc.gov.uk/information/using-check-provider>

<https://www.ncsc.gov.uk/guidance/penetration-testing>

The supplier shall not charge a premium to buyers for any additional standards and/or security compliance applicable to a call off contract, unless otherwise agreed in advance by buyers.

## 10. Location of supplier premises and liability for sub-contractors

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The location of the supplier's premises (including the location of premises at which any subcontracted components of the service are provided) is not critical to this contract, but test samples and results must be processed within UK laboratories.

It is, however, essential that regardless of such locations, the service is delivered entirely in accordance with this specification. This includes an obligation on the supplier to ensure that any sub-contractors comply fully with the requirements of the specification and the contract (the supplier will be held liable for the failure to comply by any sub-contractor). The supplier will be required to attend monthly management meetings with the DHSC. DHSC may also pay a visit to a supplier site or sites at least once during the period of the contract.

## 11. Volumes and Value

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### SECTION TO BE UPDATED FOLLOWING MARKET ENGAGEMENT

For the private Beta phase, we estimate a minimum of 1,300 cholesterol and 260 HbA1c self-sampling tests to be completed with a valid result, however, this may fluctuate depending on demand, error rate and no-completers. The service will need to be able to manage peaks in demand while maintaining a quality service.

It is anticipated that a maximum of X,XXX cholesterol tests and X,XXX HbA1c tests may be required over the initial term of the contract.

The initial period of the contract will cover the private Beta phase of the development of the digital NHS Health Check. The private Beta phase is planned to last 6 months, from xxxx to xxx.

During this phase, the maximum value of the contract is estimated to be £XXX,XXX.

It's important to note that if the contract is extended beyond the initial 6-month period, the maximum value of the contract will be increased to £xxxx. This adjustment allows for flexibility and scalability in case the project requires an extended timeframe to achieve its objectives.

## 12. Contract Period

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### SECTION TO BE UPDATED FOLLOWING MARKET ENGAGEMENT

The contract will be in place an initial period of xxxx months for the private Beta phase. We estimate this to require:

1. X months of set up, testing and integration
2. X months of delivering the service

The Department of Health and Social Care may at its own discretion extend the initial term of the contract for a further period or periods of up to 12 months. Any subsequent extension to the contract will be agreed between the Department of Health and Social Care and the Supplier. For any extension(s) to the contract, discussions with Suppliers shall be conducted sufficiently far in advance of the contract expiry date.

## 13. Contract Management and Reporting

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The Department of Health and Social Care Personalise Prevention team will manage the contract.

On a monthly basis, the Department of Health and Social Care will hold review meetings with the supplier to formally performance review the operation of the Service and discuss matters which may include but are not be limited to;

- Contract implementation
- Key service outcomes;
- Review the number of tests being processed
- Feedback from the Department;
- Discuss any complaints of poor performance and agreement of actions to address those;
- Consideration of any improvements or developments;
- Any changes in key personnel, business structure and in the market.

The supplier will be expected to field the appropriate personnel accordingly.

## 14. Contractor general responsibilities

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The Contractor shall:

- Appoint a contact to oversee the project and liaise with and report to the Department of Health and Social Care and the Department's delivery partner.
- Produce performance reports against KPIs monthly and as required by the Department of Health and Social Care
- Attend performance review meetings monthly and as required
- Perform quality assurance on all aspects of the service



- Provide timely and on-going evaluation and quality assurance information relating to the programme
- Engage in the digital NHS Health Check evaluation as and when necessary (e.g. in research interviews) on the opportunities and challenges they faced supporting the digital NHSHC programme?
- Provide updates on a monthly basis on volume of usage to the Department of Health and Social Care
- Share their annual UKAS reports and reports from any other accreditation inspection.
- Be subject to annual, formal visits from a team of pathology services quality management experts
- Provide management information when required to support Government reporting obligations or initiatives which currently include increasing direct and indirect expenditure with small and medium enterprises (SMEs), meeting the Public Sector Equality Duty and complying with government buying standards around environmental performance.

## 15. Personnel skills and knowledge

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The supplier will be expected to field the appropriate personnel accordingly.

The supplier shall ensure that all supplier staff are suitably experienced, skilled and/or qualified to deliver the services for which they are employed.

Supplier staff delivering the cholesterol and HbA1c self-sampling services must have successfully completed nationally accredited training according to their scope of practice and fulfilled relevant update requirements.

## 16. Contract monitoring

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The supplier shall provide a suitably qualified lead manager. The lead manager shall have a detailed understanding of the contract and shall have experience of managing contracts of similar size and complexity. Any changes to the lead manager shall be communicated to the buyer no less than one month in advance of any planned changes.

The lead manager shall be the primary point of contact between the supplier and the buyer and shall be responsible for managing the relationship with the Buyer which shall include:

- Contract administration
- Provision of management information
- Attending contract review meetings
- Resolution of complaints and queries
- Service planning, monitoring and continuous improvement.
- Escalating any issues that cannot be resolved between the supplier and the buyer.

The general provision, delivery, and compliance will be monitored by:

### Operational team:

The operational team (OT) will include the buyer and supplier key authorised representatives, including contract manager. The OT will meet on at least a monthly basis. The meetings will focus on technical service progress and any other issues related to the



operational aspects of the service. The operational key contacts are specified in the contract. Any initial discussion or issues related to the service should be channelled in first instance through these meetings.

The meetings discussions may include but are not be limited to;

- Key service outcomes;
- A review of the amount of business transacted under the contract as per the Management Information;
- Feedback from private Beta local authorities
- Discuss any complaints of poor performance and agreement of actions to address those;
- Consideration of any improvements or developments;
- Any changes in key personnel, business structure and in the market.

Quarterly reviews:

The supplier contract management contacts, DHSC designated policy personnel and commercial directorate, where required, will meet at the end of every financial year quarter (regardless of the starting date of the contract). Quarterly contract management will focus to formally performance review KPIs, payments, risks and any other ad hoc issues raised by the parties.

## 17. Information provision

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On a monthly basis, the supplier will be required to report progress against all the quality outcome indicators detailed under section 18.

The Department of Health and Social Care, will require the supplier to produce and submit reports detailing their performance against the service quality indicators (as described in section 18. KPIs. The right is reserved to amend the indicators from time to time to monitor different aspects of the service and also to undertake verification audits if required.

Where a monthly report to the Department detailing recent and cumulative activity indicate that the number of kits issued and/or tested is approaching the maximum estimated value of the contract an alert shall be sent to the DHSC operational team.

The Department of Health and Social Care receive information about usage at least [time frame] via a secure mechanism. Levels of access shall be controlled to limit the data visible (in particular such access shall automatically manage controls required under relevant legislation, for example, as applies to data protection and patient confidentiality).

**A.1** The parties will discuss information reports on monthly basics.

## 18. Key performance indicators (KPIs)

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Quality outcomes indicators

In order to secure maximum effectiveness from the contract in terms of delivering against its overarching objectives, the supplier's performance will be monitored against relevant quality outcomes indicators. The following table sets out various such indicators, data should be broken down by test type (cholesterol or HbA1c),

#	Indicator	Good (=Target)	Approaching Target	Requires Improvement	Inadequacy (=Critical Service Level Failure)
1	Percentage of kits packaged and posted to service user within 2 working days of request	95%	95-90%	90-80%	<80%*
2	Percentage of self-sampling specimens returned to the laboratory by service user for processing within 30 days of receipt	>60%	60-50%	50-40%	<40%
3	Percentage of self-sampled specimens that could not be processed by the laboratory due to being insufficient therefore requiring a repeat kit	<8%	8-10%	10-15%	>15%
4	Percentage of self-sampled specimens that could not be processed by the laboratory due to being haemolysed therefore requiring a repeat kit	<8%	8-10%	10-15%	>15%
4	Percentage of self-sampled specimens that are processed and analysed within 2 working days.	100%	<100-90%	<90-80%	<80%*
5	Percentage of results communicated back to the digital service within 3 working days of receiving the self-sample.	100%	<100-90%	<90-80%	<80%
6	Percentage of complaints received from service users (this will be through the digital check)	<5%	5-7%	>7-10%	>10%
7	Data breaches (including cyber attacks) communicated to DHSC within 10 hours of being known to the Supplier	100%	<100-95%	<95-85%	<85%