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| **National Pathology and Diagnostics UTL & FHIR Testing** |
| ***Supplier Test Approach*** |
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1. **Introduction**

The purpose of this Test Approach document is to set out the testing principles and to provide the information necessary to plan and control the test effort for National Pathology & diagnostics Programme. It describes the standards for the testing processes and provides the overarching plan for the direction of the suppliers' test effort.

It is intended that this approach document will be used as a reference. More detailed test plans will be created for the phases of the programme. This Test Approach document will be shared with all parties, and it is expected that all will agree to adhere to the principles outlined throughout this programme.

The document includes:

* The high-level approach to testing & Assurance
* The roles and responsibilities
* The test deliverables
* The different test levels and test types

This document is based on the testing knowledge outlined by the International Software Testing Qualifications Board (ISTQB). [[1]](#footnote-1)

1. **Programme overview**

South, Central and West have been engaged to deliver the capability to share pathology results across the health and care sectors. The programme will specifically deliver a series of test on the existing messaging systems with the aim of producing a retrospective case study for the end client.

The National Pathology and Diagnostics work defined three broad areas of information standards to meet future NHS needs for interoperability and secondary care use:

* Unified Test List (UTL) – a national catalogue of Pathology test requests and results to replace the Pathology Bounded Code List (PBCL), based on SNOMED CT
* Units of Measure (UoM) – an unambiguous representation of commonly used units, aligned with the UTL, based on Unified Code for Units of Measure (UCUM)
* Pathology Message Specification – for interoperable data exchange of Pathology information to replace the Pathology Messaging Implementation Programme (PMIP) ISB 1557 EDIFACT Pathology Messaging (NHS003), based on Health Level 7 (HL7) Fast Healthcare Interoperability Resources (FHIR)

The National Pathology Diagnostics Programme is looking to establish collaborations in interoperability and information standardisation for key pathology initiatives across Health and Social Care to agree an approach for moving existing pathology estate and infrastructure to a future state based on updated national standards.

1. **Terminology used in this document**

In this document **‘Fast Healthcare Interoperability Resources’** is used when describing generic capabilities or principles for a supplier-based product.

SCW CSU is responsible for the overall project & Test management and suppliers are responsible for their own testing, using this document as guidance.

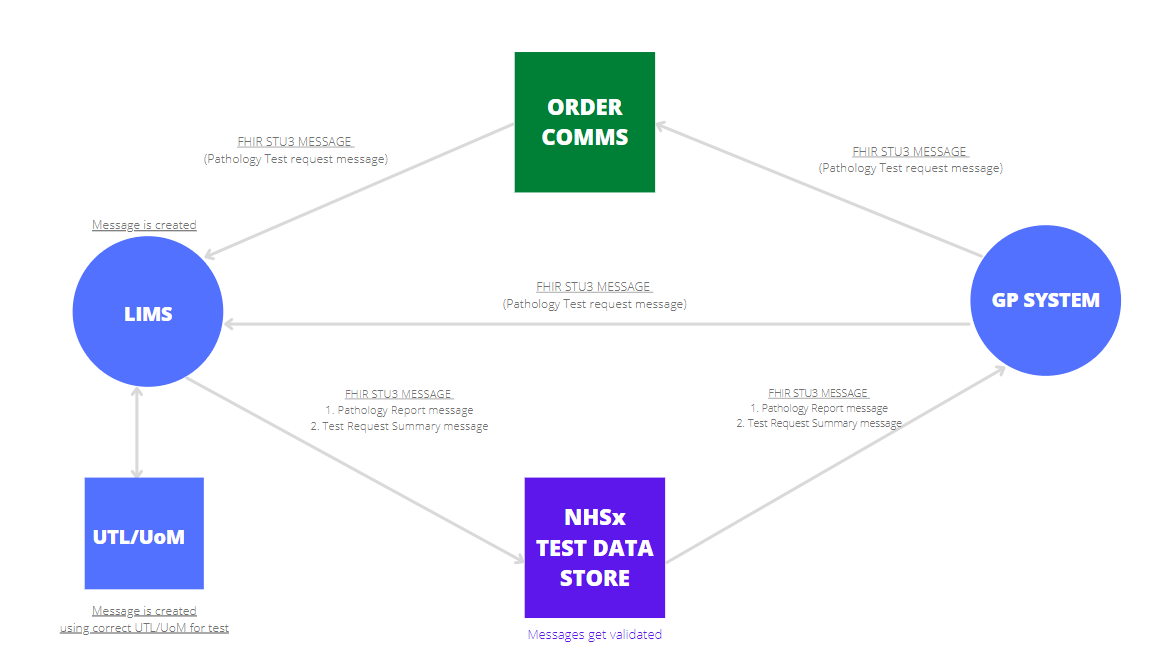
1. **Testing scope**

### In scope

A test item is a feature or an area which requires testing. The expected test items are listed below:

| Feature/Area | Description | Testing responsibility |
| --- | --- | --- |
| Messaging – GP system Sending of Pathology Test Request messages | This covers testing the ability of the GP supplier to successfully send a Pathology Request message to LIMS system. In some cases the GP Supplier may send the request to the LIMS system via an order comms system | GP System Supplier,  (If applicable – Order comms Supplier) |
| Messaging – LIMS Sending of Pathology Test Report messages | This covers testing the ability of the LIMS supplier to successfully send a Pathology Report message to a GP system via the \*Test Data Store  *\*For testing purposes this message will be sent to a Test Data store (FHIR Server) – developed by SCW* ) | LIMS System Supplier |
| Messaging – LIMS Sending of Pathology Test Request summary messages | This covers testing the ability of the LIMS supplier to successfully send an associated ‘Test Request’ summary message to a GP system via the \*Test Data Store  *Note: Test request summary message provides information around which ‘test request’ messages have come in, and what ‘reports’ have been generated as a result of those requests.* | LIMS System Supplier |
| Messaging – Receiving\Consuming of Pathology Test Reports & Test summary requests | This covers testing the ability of the GP supplier to successfully receive/consume a ‘Pathology reports’ & ‘request summary’ message from a LIMS system via a data store into a GP system  (*For testing purposes this message will be sent via a Test Data store (FHIR Server) – developed by SCW*) | GP System Supplier |
| Unified Test List | Testing to ensure that valid UTL codes are present during the sending/receiving of results between ‘Lab’ and ‘GP Systems for a selected number of ‘Pathology Report’ tests.  UTL codes to be based on the latest list [Release\_v\_0.6.0\_20210127](https://hscic.kahootz.com/connect.ti/PathologyandDiagnostics/view?objectId=66089349#66089349) | ALL |
| Units of Measure (UoM) | Testing to ensure that valid Units of Measure (UoM) align with the correct UTL codes during the sending/receiving of results between ‘Lab’ and ‘GP Systems for a selected number of ‘Pathology report’ tests.  UoM should be based on the latest version of the ‘Unified Code for units of measure’ (UCUM). | ALL |
| FHIR message standards[[2]](#footnote-2) | SCW via a test data store (test FHIR server) will validate that LIMS sending results systems & GP result  Receiving systems have the correct message structure.  For example validating that a message has all the appropriate mandatory/optional elements. | ALL |

**Figure A** has been provided below to help visualise the End to End testing scope items mentioned in the above table. However, at the moment testing is decoupled and not running in a particular sequence:



**Figure A:** Testing scope

### Out of scope

The following items are out of scope for this test approach:

| Feature/Area | Description |
| --- | --- |
| MESH | Currently testing not supporting the sending/receiving of messages over MESH. However, there may be future requirement to send/receive via MESH. |
| Unified Test List – Full exhaustive list | Although as per section 4.1 above, testing will include to ensure valid UTL codes are present within the Pathology test results message. Testing the full exhaustive list of UTL codes is not in scope here, instead with consultation of Pathologists/Suppliers testing will look to select a representative selection of tests listed in the UTL only. |
| Presentation of Pathology test results | It will be the testing responsibility of the GP systems supplier, to ensure that the presentation and format of the pathology test results are visible and readable to the end user. |
| Units of Measure (UoM) - Full exhaustive list | Although as per section 4.1 above, testing will include to ensure valid Unit of measurements (UoM) are present within the Pathology test report message. Testing the full exhaustive list of UoM codes is not in scope here, instead with consultation of Pathologists/Suppliers testing will look to select a representative selection of tests. |

1. **Roles and responsibilities**

SCW Testing Lead will be responsible for leading and overseeing the LIMS & GP system Supplier testing for the National Pathology diagnostics programme. This section outlines the responsibilities for SCW and Suppliers. The roles and responsibilities for the testing lifecycle main tasks can be found in Appendix 13.2.

### NHSX Testing Lead

* Creating a Test Approach to cover the testing principles for the National Pathology Diagnostics Programme
* Identifying & providing a candidate list of Test cases to both LIMS & GP system suppliers covering the in-scope messages for testing
* Providing a defect template and priority levels for logging/recording and prioritising defect/issues found during testing to the Suppliers (Also discussed within section 13 of this document). Completed defect templates by the supplier will be uploaded into the SCW test management tool
* Facilitating of Supplier Access/connections to any SCW test automation tools (i.e. Test data store server)
* Signposting Suppliers to appropriate teams/contacts from NHS Digital in regard to any challenges/queries around FHIR
* Reviewing Supplier testing evidence such as test messages
* Monitoring supplier daily testing execution progress via regular updates
* Facilitating a testing start (kick-off) and testing end (wash-up) meetings with supplier to review progress against testing exit criteria
* Review of any Final test reports created by Supplier
* Facilitating testing lessons learnt session via online or face to face meetings to share testing experiences

### Supplier

* GP system suppliers to ensure their test systems can send ‘Pathology test request’ messages to Order comms and/or LIMS systems
* LIMS suppliers to ensure that they can consume ‘Pathology test request’ messages from GP Suppliers systems
* LIMS suppliers to create ‘Pathology test report’ messages in response to the ‘Pathology test request’ message. Covering the test list (as mentioned in point 2 – section 5.1)
* GP system suppliers to ensure test systems can consume LIMS ‘Pathology test report’ messages
* Provide regular updates during test execution to SCW Test Lead
* Complete the defect template and provide to SCW Test Lead
* Own overall defect/issue list
* Responsible for providing sight of any final test reports to SCW and ensuring final test exit criteria has been met.

### NHS Digital

* Responsible as a point of contact with regards to any FHIR specific message enquiries
* Responsible for resolving any FHIR related message/issues

1. **Programme test approach**

This section describes the overall approach to testing as part of the National Pathology Diagnostics Programme and the types of testing undertaken at specific points of the development lifecycle.

The objectives of software testing are:

* To validate and verify system functionality works to the specified requirements
* To validate and verify that functionality is acceptable to end users
* To identify defects that may get created during the development of new functionality
* Assess readiness of the system for go live
* To reduce risk
* To gain confidence in the quality of the software

The testing approach for all suppliers will follow the “V Model” software development methodology This will enable test planning and documentation early in the programme lifecycle and aims to mitigate the impact of product defects early in the development process.

### Test Phases

The test phase provides an indication of the focus of the testing and the types of problems that it is likely to uncover. Appendix 13.5 provides a brief overview of each test phase.

Static testing will also be conducted throughout the testing lifecycle.See Appendix 13.6.

### Planning

It will be the responsibility of the Supplier testing the functionality to define their own test schedules and to complete the testing within defined testing periods.

High level information on the phases can be found in Appendix 13.7. A more detailed test schedule should be included in any Supplier specific test plans.

### Test deliverables

The test deliverables for this programme are outline in Appendix 13.8.

### Test tools

A test tool is a piece of software that is used to make the testing process more effective and efficient.

A number of test tools have been identified to support the testing activity. These tools are summarised in Appendix 13.9.

### Test data

Where test data is required for the execution of test scenarios this will be created prior to testing and agreed with input from Supplier. The requirements for data for each test will be defined against each test case.

Once test data requirements has been defined, then the potential options for sourcing test data could potentially be:

1. Supplier based test data (i.e. LIMS/GP System suppliers may have existing test messages/data from previous testing)
2. Pathologist created synthetic test data
3. NHS Digital based pathology test data

It is the responsibility of each Supplier to ensure test data is being used appropriately and in accordance with the appropriate Information governance guidelines.

1. **Assumptions**

The commencement of testing for each phase is based on the following **assumptions**:

|  |  |
| --- | --- |
| **Testing Documentation** | * Scope\Requirements agreed and signed off * Test approach completed and agreed by all involved in testing * Testing schedule/dates agreed with appropriate parties * Testing documentation templates shared with all parties * Test scripts created * Suppliers have allocated test resources once requirements known * Suppliers will use the agreed defect priority levels and agreed defect management process |
| **Test Data** | * Test data will be synthetic where possible. * Live Data will not be used for testing |
| **Testing readiness** | * Test user accounts setup for testing * The relevant software environments are available and accessible * The Supplier has identified testing resource is available to complete the tests as per the schedule |
| **Test Execution** | * If testing extends beyond the planned timetable, all stakeholders will mutually agree any changes that are needed to facilitate successful completion of testing |
| **Test Cycle Sign Off** | * Entry/Exit criteria have been met for each phase when moving onto the next phase or go-live with no critical or major errors (POs P1s) outstanding |

1. **Entry and exit criteria**

The high level criteria for each phase of the slot plan can be found in the following table. More detailed Entry and Exit criteria will be included in each phase test plan.

| **Testing Area** | **Entry Criteria** | **Exit criteria** |
| --- | --- | --- |
| GP system – Sending of Pathology requests to LIMS | * SCW Test Approach signed off * SCW provided Test cases completed * Supplier Test Data setup * Supplier Test Environment setup complete | * Test Scripts completed * Test messages\evidence provided to SCW * No Critical (P0) or Major (P1) defects/issues outstanding * An agreed work-off plan for remaining minor issues * Final Testing Report provided to SCW/NHSD |
|
|
| LIMS system – Sending of Pathology Reports to GP system via  (NHSx Test Data Store) | * SCW Test Approach signed off * SCW provided Test cases completed * Supplier Test Data setup   Supplier Test Environment setup complete | * Test Scripts completed * Test messages\evidence provided to SCW * No Critical (P0) or Major (P1) defects/issues outstanding * An agreed work-off plan for remaining minor issues * Final Testing Report provided to SCW/NHSD |
|
|
| GP system - consuming Pathology Reports sent from Test Data Store | * SCW Test Approach signed off * SCW provided Test cases completed * Supplier Test Data setup   Supplier Test Environment setup complete | * Test Scripts completed * Test messages\evidence provided to SCW * No Critical (P0) or Major (P1) defects/issues outstanding * An agreed work-off plan for remaining minor issues   Final Testing Report provided to SCW/NHSD |

1. **Approvals**

This section details the approval/sign off to be sought at each stage.

* Each Supplier will be responsible for ensuring appropriate testing sign off for their End to End Functionality with SCW Testing Lead. They will also be responsible for completing a test report for the testing of this functionality
* Any outstanding issues/defects found during the testing which require prioritisation from all parties will be reviewed and discussed via a call with SCW programme
* Test Report for testing to be approved by SCW Programme & Workstream lead
* Programme managers must come to consensus regarding sign off and agreement to release to the Production environment. If a consensus cannot be reach the programme managers will escalate to Programme Board
* Programme managers should ensure that the governance processes are followed prior to Go Live/Launch
* The final sign off before Go Live/ Launch will be provided by the Programme board via the work stream leads

1. **Suspension and resumption criteria**

Testing may be suspended for the following reasons:

* A high priority test issue is found which prevents the remaining test cases from being completed
* The test environment is unavailable or unstable
* The testing resource is unavailable

A recommendation for test suspension will be mutually agreed Suppliers and SCW, NHS Digital. This will include any implications on the overall slot plan. All stakeholders involved in testing will be informed.

A resolution plan will be created with input from stakeholders to resolve the issue identified. A recommendation to resume test execution will be mutually agreed between Suppliers, SCW and NHS Digital.

1. **Defect management procedure**

A Summary is below:

* A defect/issue is an unexpected result that occurs during testing which requires further investigation and resolution
* All defects/issues identified during test execution must be logged using the agreed defect/issue template which will be provided to all Suppliers by NHSX Test Lead, It is intended by standardising the recording of defects this will make programme and phase test analytics easier to collect
* Defect management tools will be used to record and track the progress of defects. NHSX will use Target Process to log issues
* All fixes on the backlog will be planned into future development releases and agreed with all suppliers as appropriate
* Defects must be completed using the defect template (excel) see appendix 13:1

### Test & defect communication

During test execution of each test phase there will be regular reporting of testing progress between Supplier and SCW programme\testing lead.

Brief testing updates will be provided during by means of a regular calls/Online conferencing.

1. **Testing environment**

This section describes the physical environments that are used in the testing process.

### Software Environments

Environments to be confirmed

| **Environment** | **Link/URL/Port details** |
| --- | --- |
| Supplier Test environment LIMS | tbc |
| Supplier Test environment GP | tbc |
| FHIR Server (NHSx Test Store) | tbc |
| Supplier Test enviornment (Order comms – if applicable) | tbc |

### Software/Hardware requirements

We expect suppliers to support the following browsers and operating Systems:

| **Software** | **Description** |
| --- | --- |
| Internet Browser | Supported browsers\*\*:   * Internet Explorer 10 * Internet Explorer 11 * Microsoft Edge * Firefox * Chrome * Safari 9+   Supported Operating Systems\*\*:   * Android * IOS * MacOS * Windows |

\*\* browsers\operating systems to be confirmed.

1. **Appendix**

### Document references

### RACI matrix

| Testing Activity | SCW Digital PM | Supplier Test Lead | SCW Test Lead | NHS Digital |
| --- | --- | --- | --- | --- |
| Test Approach Design | I | C | R | I |
| Test documentation templates | C | C | A | N/A |
| Test environment setup | I | R | I | N/A |
| Authoring Test Cases/scripts  (Phase 1 – Integration Testing) | C | A | R | N/A |
| Provision of test data (Phase 1) | I | A | C | I |
| Phase 1 Integration - Test Execution | I | A | I | I |
| Phase 1 Integration - Test Evidence | I | A | I | I |
| Authoring Test Cases /scripts (Phase 2 Integration) | I | A | R | I |
| Provision of test data (Phase 2) | I | A | C | I |
| Phase 2 Integration - Test Execution | I | A | I | I |
| Phase 2 Integration – Test Evidence | I | A | I | I |
| Phase 3 Integration - Test Execution | I | A | I | I |
| Phase 3 Integration – Test Evidence | I | A | I | I |
| Defect management \*\* | I | R | R | I |
| Production of final test report including lessons learnt \* | I | A | R | I |

|  |
| --- |
| Key:  **R - Responsible** –Responsible for completing the work to achieve the task.  **A - Accountable** – Accountable for the completion and sign off of a task  **C - Consulted** – Not directly involved in carrying out the task but are consulted such as subject matter experts or for review of documentation.  **I - Informed** – Notified of progress such as the completion of a task. |

\* This can be a singular report produced by the Supplier covering all test phases (Unit/integration/System end-to-end)

\*\* NHSX will be responsible for providing guidance around the defect management process, and Supplier will be responsible for following through the process during test execution.

The following people have been identified for the roles listed above:

|  |  |  |
| --- | --- | --- |
| **Role** | **Person** | **Organisation** |
| Programme | Andrew Payne | SCW |
| SCW Test lead | Haaris Siddiqie | SCW CSU |
| TBC | TBC | GP systems Supplier |
| TBC | TBC | LIMS systems Supplier |

### Testing terminology / glossary

|  |  |
| --- | --- |
| **Term** | **Description** |
| **End-to-end testing** | Tests the complete solution; covering messaging, portal, roles and patient matching, tests and results. |
| **Functional testing** | Testing based on an analysis of the specification of the functionality of a component or system. |
| **Integration testing** | Testing performed to expose defects in the interfaces and in the interactions between integrated components or systems. |
| **Interoperability** | For the purpose of this document interoperability refers to the interfaces built to share data with the Pathology system |
| **Operational acceptance testing** | Testing performed in a (simulated) operational environment by operations / system administration staff focusing on operational aspects. |
| **Performance testing** | Testing based on determining the speed or effectiveness of the system. |
| **Regression testing** | Testing of a previously tested program following modification to ensure that defects have not been introduced or uncovered in unchanged areas of the software as a result of the changes made. It is performed when the software or its environment is changed. |
| **Smoke test** | A subset of all defined/planned test cases that cover the main functionality of a component or system, to ascertain that the most crucial functions of a program work. |
| **System integration testing** | Testing the integration of systems and packages; testing interfaces to external organisations. |
| **System testing** | Testing an integrated system to verify that it meets specified requirements. |
| **Technical testing** | Testing based on the data feeds and ensuring that messaging and content are being processed correctly. |
| **Test case** | A set of input values, execution preconditions, expected results and execution post conditions, developed for test condition(s), to verify compliance with a specific requirement. |
| **Test condition** | An item or event of a component or system that could be verified by one or more test cases e.g. a function or feature of the system. |
| **Test script** | A document specifying the test conditions (coverage items) for a test item, the detailed test approach and identifying the associated high-level test cases. It is a set of instructions to execute a test. |
| **Unit testing** | Testing units or components as each component is built. It is the smallest testable part of an application. |
| **User acceptance testing (UAT)** | Acceptance testing carried out by future users in a (simulated) operational environment focusing on user requirements and needs. |

### Clinical safety assessment

The objective of clinical safety assessment is to identify any potential clinical risks from a product and provide mitigation for these risks. SUPPLIER will be responsible for undertaking a clinical safety assessment SCCI0129 and providing evidence to support the testing process particularly for later phases of the programme.

### Test phases & Types

The test phase provides an indication of the focus of the testing and the types of problems that it is likely to uncover. The table below provides a brief overview of each test phase:

| **Test Phase** | **Description** | **Who would do this?** |
| --- | --- | --- |
| **Integration Testing** | Once each individual unit has been developed, this stage would put them together to create a system.  The purpose of this testing is to expose defects in interfaces and integrated systems  An example would be testing to ensure LIMS or GP system communicates with Test Store (FHIR Server) | This is will be carried out by the Tester (Supplier) and evidence provided |

### Static testing

Static testing is a type of testing that does not involve testing software by executing the code, but takes the form of inspections, walkthroughs and reviews. It more commonly known as quality assurance and is carried out throughout the entire programme lifecycle.

The objective of static testing is to assess whether programme specifications meet the criteria defined for testability. This provides an early opportunity to highlight any discrepancies and allow defects to be corrected in the specification before the development is completed.

Documents to be reviewed include:

* Acceptance criteria

• Test Plans

• Test Scripts

• Release Notes

• Test Summary Report

### Test Deliverables

| **Test deliverable (product)** | **Description** | **When is it used?** |
| --- | --- | --- |
| Test approach (this document) | The document that outlines the high level test approach for this programme. It identifies the test process and roles and responsibilities for testing | Prior to test execution |
| Test Plan (for each phase/test cycle) | The document that contains detailed information for testing to be completed as part of a specific phase in the programme. It identifies the items to be tested, who will do the testing, the pass/fail criteria and the testing schedule. The **entry** and **exit** criteria are defined in the test plan | It is used throughout the test planning process |
| Test pre-requisite checklist | A checklist used to confirm practical test readiness. This checklist can be used by each Supplier to check the status of key tasks required before test execution | Prior to test execution |
| Test Cases | Test cases contain the detail of what test conditions will be tested, the expected outcomes and the definition of any test data required to execute the tests  Test cases will cover the scenarios for end to end testing | During test analysis and design |
| Test scripts | The set of instructions that enable the test case to carried out. For each test scenario there will be one test script  Testers will be expected to mark the test scripts as passed or failed | During test execution |
| Testing schedule | The detailed plan of when testing will take place and who will be doing it | Defined during test planning and used during test execution |
| Issues Log | Log of all defects raised during testing  Supplier will be responsible for providing a comprehensive list of all issues logged from all sites  This will also include known issues from unit testing | During test execution |
| Test Report | A test report will be completed at each test phase by the tester responsible for testing and include any appropriate sign off sought. The test certificate will summarise the testing activity and results and advise if the **exit criteria** has been meet  A test certificate will also include any outstanding issues and the agreed work off plan | During the Evaluating exit criteria and reporting stage |

### Test tools

| **Tool Name** | **Used For** |
| --- | --- |
| Target Process | * SCW Recording test cases and detailed test steps for testing completed by SCW Test Lead * Recording test results for testing completed by Supplier * Linking any defects found to the relevant test case/ script * Providing traceability from requirements through to closure * Defect management for testing completed by Supplier * Test reporting for testing completed by Supplier |
| MS Excel | * Initial documentation of test conditions, cases and scripts * Sharing defects/issues to distribute between Suppliers * Production of test schedule template * Test script and defect templates for use by all Suppliers |
| Test Store (NHSx) | * Store and validate test messages from LIMS * Send test messages to GP systems |

. All test script templates and key deliverables will be provided in Excel format.

### Document change history

|  |  |  |  |
| --- | --- | --- | --- |
| Document Change History | | | |
| **Version** | **Date** | **Contributing authors** | Comments |
| 0.1 For review | 28.04.2021 | Draft issue | For stakeholder review |
| 1.0 | 26.05.2021 | Andrew Payne | 1.Included test requests back into scope  2. As this Proof of concept , removed defect priority levels  3. Amended testing scope figure A diagram  4. Included ‘Order comms’ into scope |
| 2.0 | 15.06.2021 | Haaris Siddiqie | Removed references to ‘Phases’ as testing is decoupled and not in a particular sequence. |

|  |  |  |
| --- | --- | --- |
| Distribution Table for final version | | |
| **Name** | **Role** | **Organisation** |
| Andrew Payne | Lead Architect | SCW |
| **Haaris Siddiqie** | Test Specialist | SCW |
| Emlyn Jones | Interoperability Architect | SCW |
| Richard Sutcliffe | Product Manager | NHS Digital |
| Phillip Brennan | Lead Business Analyst | NHS Digital |

1. ISTQB are a not-for-profit organisation that has defined the “ISTQB certified Tester” scheme, which is the worldwide leader in certification of competences in software testing. [↑](#footnote-ref-1)
2. FHIR Interoperability Resources [↑](#footnote-ref-2)