Supplementary Protocol

Host Interface Specification

Guide to establish systems and processes to send test results from QIAreach™ Software to LIMS

Intended use

This document describes the communications method between QIAreach Software and the structure of the results output file.

Table 1 describes the abbreviations used throughout this document.

Table 1. List of abbreviations

Term	Description
CSV	Comma-separated values used for the digital storage of data structured in a table of lists form
MDS	Used to verify the integrity of files
LIMS	Laboratory Information Management System
ISO	International Standards Organization
Ag	Antigen
Ig	Immunoglobin
LIONC	Logical Observation Identifiers Names and Codes
SNOMED	Systematized Nomenclature of Medicine
SMB	Server Message Block

Intended user

This guide provides information needed by Information Technology (IT) personnel for establishing the systems and processes to send test result files from QIAreach Software to a Laboratory Information Management System (LIMS).

Communication overview

The QIAreach Software outputs the test result data as CSV files. The files are designed for easy processing by all LIMS. It is also intended as a human-readable file to use in test settings where LIMS are not available and manual processing may be required.

The QIAreach Software uses a push/pull concept wherein test results are pushed to a shared file folder accessible through the Windows API. The shared folder can be found on the Local Area Network (LAN) and connected using the Server Message Block (SMB). CSV files ready for transmission are pushed every 10 seconds. The computer where the QIAreach Software is installed must have the Read and Write permissions to the shared folder. The LIMS is then responsible for the collection and parsing of the CSV files to complete the data transfer. The LIMS must have a Read and Write permission to the shared folder.
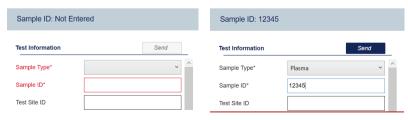
Definition of Valid test results

The QIAreach Software defines a test result as Valid if it meet the following criteria:

- The test run is completed.
- The test run did not result to an error.

Definition of files ready for transmission

The QIAreach Software will only queue a valid test result for transmission if it meets the following criteria:

- Mandatory data fields for each test are populated (i.e. Sample Type and Sample ID).
- A valid LIMS folder path is defined and saved. Files will not be queued or sent if the LIMS folder path is invalid or undefined.
- The Send option is enabled. This is indicated by a blue Send button.

Send button gray (sending not enabled)   Send button blue (sending enabled)

CSV files overview

Clicking the Send button enables the QIAreach Software to create one CSV file per valid test result. Each CSV result file is queued for transmission. The CSV file is encoded in a UTF-8 format.

The CSV file contains a header row describing the contents in row 1 with the data in row 2.

Automatically exported results filename

- DateTime_AssayType_SampleID_eStickSerialNumber_Result
- Example: 2020-10-16T09-02-31_AntiCoV2_56456_54414285_Positive (+)

Unsupported characters

The CSV result filename incorporates the Sample ID. However, some characters are unsupported to maintain compatibility with Windows file naming convention. The unsupported characters include the following: "%&*:<>?/\{|},

The unsupported characters used in Sample IDs will be replaced with ~ in the CSV result filename.

md5 files

Along with each CSV result file sent to the shared folder, an md5 hash file is also created and sent to the shared folder. The md5 hash functions as a compact digital fingerprint of a file to verify that the result files has not changed as a result of a faulty file transfer or disk error. The use of the md5 file is only to protect the data integrity against non-intentional corruption rather than as a cryptographic hash function.

Note: The md5 file follows the same filename structure and content of its counterpart CSV file. An example of an md5 filename is 2020-10-16T09-02-31_AntiCoV2_56456_54414285_Positive (+).csv.md5.

Important: A .csv and .csv.md5 pair of file should only be considered valid if the md5 sum over the .csv file is equal to the content of the md5 file. This safeguards against incompletely written files or transmission errors.

Dynamic structure of CSV files

The QIAreach Software can support a variety of eStick assays. For each assay, pre-defined fields are available for the user to collect data that may be beneficial for clinical or surveillance purposes. The CSV result file only includes data fields that are specific to the assay used. The LIMS parsing will need to operate on the basis of matching column headers by name rather than by position within the CSV file.

Data types

Table 2 describes the used formats.

Table 2. Used data types

Data type	Format	Description
<date>	Date	Information about a point in time Note: Refer to ISO 8601 for a detailed description of the format used in CSV. In CSV files, this format is used: YYYY-MM-DD Example: 2009-11-17
<datetime>	Date and time	Information about a point in time Note: All points in time are in UTC. Refer to ISO 8601 for a detailed description of the format used in CSV. Note: Due to time changes between summer and winter time, UTC times shift as well, e.g 7AM CE(S)T equals 5AM UTC during summer period, and 6AM in winter period. Example: 2018-08-01T16:53:45 UTC offset is also included and represented as +/- UTC. Example: 2020-10-16T09:39:19+3:00
<string>	Alphanumeric string	Used for text information

Data fields

Table 3 describes all used fields in the integration.

Table 3. Used data fields

Fieldname	Description*	Example	Assay	Generated by
Test type	Names of the assay used • Anti-CoV2 • CoV2 Ag • QIAreach QFT	CoV2 Ag	All	User
Test type LOINC	LOINC code of Test Type used	94558-4	Ag	System
eStick Serial Number	Serial number of eStick	69894631	All	System
Result	Result of the test: • Positive (+) • Negative (-) • Error**	Positive (+)	All	System
Result SNOMED	SNOMED code associated with result Assay dependent	10828004^Positive^SCT	Ig, Ag	System
Time to Result – Seconds	Time in seconds takes to produce a valid result	240	All	System
Test Run Date – Time	Test run date-time in UTC	2020-10-16T09:39:19+01:00	All	System
eStick Expiry Date	Expiry date of eStick in UTC	2021-12-31	All	System
Sample type	Sample type used for test Assay development • Plasma • Serum • NasalSwab • NasopharyngealSwab • Other**	Plasma	All	User
Sample Type SNOMED	SNOMED code associated with sample type	119361006^Plasmaspecimen^SCT	All	System

* Indicates possible values

** See *QIAreach Software User Manual.*

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Table 3. Used data fields (cont'd)

Fieldname	Description*	Example	Assay	Generated by
Sample ID	Sample ID used for test†	857578975	All	User
Test Site ID	Test site identifier†	Central Laboratory	All	User
Operator ID	Test operator identifier†	John Smith	All	User
Collection Site ID	Identifier of site where sample was collected†	City Nursing Home	All	User
Sample Collection Date	Date sample was collected in UTC	2020-10-16	All	User
Kit Lot Number	Lot number of assay†	5674567	All	User
Date of Birth	Date of birth of patient in UTC	1975-02-12	All	User
Number of Days Since Symptom(s) Onset	Number of days since patient started showing symptoms	14	Ag	User
Gender	Gender of patient ● Male ● Female ● Other	Male	All	User
AssociatedSymptoms_Fever	Indication of patient showing symptoms of COVID-19 ● Yes ● No ● Unknown‡	Yes	Ig, Ag	User
AssociatedSymptoms_Cough	Indication of patient showing symptoms of COVID-19 ● Yes ● No ● Unknown‡	No	Ig, Ag	User

* Indicates possible values

† Maximum of 25 characters

‡ Used as default if not changed by user

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Table 3. Used data fields (cont'd)

Fieldname	Description*	Example	Assay	Generated by
AssociatedSymptoms_ShortnessOfBreath	Indication of patient showing symptoms of COVID-19 ● Yes ● No ● Unknown‡	Unknown	Ig, Ag	User
AssociatedSymptoms_MuscleOrBodyPain	Indication of patient showing symptoms of COVID-19 ● Yes ● No ● Unknown‡	Yes	Ig, Ag	User
AssociatedSymptoms_Fatigue	Indication of patient showing symptoms of COVID-19 ● Yes ● No ● Unknown‡	No	Ig, Ag	User
AssociatedSymptoms_Nausea	Indication of patient showing symptoms of COVID-19 ● Yes ● No ● Unknown‡	Unknown	Ig, Ag	User

* Indicates possible values

‡ Used as default if not changed by user

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Table 3. Used data fields (cont'd)

Fieldname	Description*	Example	Assay	Generated by
AssociatedSymptoms_Diarrhea	Indication of patient showing symptoms of COVID-19 ● Yes ● No ● Unknown‡	Yes	Ig, Ag	User
AssociatedSymptoms_AlteredTasteOrSmell	Indication of patient showing symptoms of COVID-19 ● Yes ● No ● Unknown‡	No	Ig, Ag	User
AssociatedSymptoms_Congestion	Indication of patient showing symptoms of COVID-19 ● Yes ● No ● Unknown‡	Unknown	Ig, Ag	User
AssociatedSymptoms_AlteredConsciousness	Indication of patient showing symptoms of COVID-19 ● Yes ● No ● Unknown‡	Unknown	Ig, Ag	User
AssociatedSymptoms_Headache	Indication of patient showing symptoms of COVID-19 ● Yes ● No Unknown‡	No	Ig, Ag	User

* Indicates possible values

‡ Used as default if not changed by user

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Table 3. Used data fields (cont'd)

Fieldname	Description*	Example	Assay	Generated by
AssociatedSymptoms_SoreThroat	Indication of patient showing symptoms of COVID-19 ● Yes ● No ● Unknown‡	Unknown	Ig, Ag	User
AssociatedSymptoms_Vomiting	Indication of patient showing symptoms of COVID-19 ● Yes ● No ● Unknown‡	Yes	Ig, Ag	User
AssociatedSymptoms_NoSymptoms	Indication of patient showing symptoms of COVID-19 ● Yes ● No ● Unknown‡	No	Ig, Ag	User
PreExistingConditions_Asthma	Indication of patient showing symptoms of COVID-19 ● Yes ● No ● Unknown‡	Yes	Ig, Ag	User
PreExistingConditions_Cancer	Indication of patient showing symptoms of COVID-19 ● Yes ● No Unknown‡	No	Ig, Ag	User

* Indicates possible values

‡ Used as default if not changed by user

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Table 3. Used data fields (cont'd)

Fieldname	Description*	Example	Assay	Generated by
PreExistingConditions_Cardiomyopathy	Indication of patient showing symptoms of COVID-19 ● Yes ● No ● Unknown‡	Unknown	Ig, Ag	User
PreExistingConditions_CerebrovascularDisease	Indication of patient showing symptoms of COVID-19 ● Yes ● No ● Unknown‡	Yes	Ig, Ag	User
PreExistingConditions_ChronicKidneyDisease	Indication of patient showing symptoms of COVID-19 ● Yes ● No ● Unknown‡	No	Ig, Ag	User
PreExistingConditions_ChronicNervousSystemDisorder	Indication of patient showing symptoms of COVID-19 ● Yes ● No ● Unknown‡	Unknown	Ig, Ag	User
PreExistingConditions_ChronicObstructiveLungDisease	Indication of patient showing symptoms of COVID-19 ● Yes ● No ● Unknown‡	Yes	Ig, Ag	User

* Indicates possible values

‡ Used as default if not changed by user

Table continued from previous page

Table 3. Used data fields (cont'd)

Fieldname	Description*	Example	Assay	Generated by
PreExistingConditions_CoronaryArteriosclerosis	Indication of patient showing symptoms of COVID-19 ● Yes ● No ● Unknown‡	No	Ig, Ag	User
PreExistingConditions_CysticFibrosis	Indication of patient showing symptoms of COVID-19 ● Yes ● No ● Unknown‡	Unknown	Ig, Ag	User
PreExistingConditions_Dementia	Indication of patient showing symptoms of COVID-19 ● Yes ● No ● Unknown‡	Yes	Ig, Ag	User
PreExistingConditions_DiabetesMellitusType1	Indication of patient showing symptoms of COVID-19 ● Yes ● No ● Unknown‡	No	Ig, Ag	User
PreExistingConditions_DiabetesMellitusType2	Indication of patient showing symptoms of COVID-19 ● Yes ● No ● Unknown‡	Unknown	Ig, Ag	User
PreExistingConditions_DiabetesMellitusType2	Indication of patient showing symptoms of COVID-19 ● Yes ● No Unknown‡	Unknown	Ig, Ag	User

* Indicates possible values

‡ Used as default if not changed by user

Table continued from previous page

Table 3. Used data fields (cont'd)

Fieldname	Description*	Example	Assay	Generated by
PreExistingConditions_DiseaseOfLiver	Indication of patient showing symptoms of COVID-19 ● Yes ● No ● Unknown‡	Yes	Ig, Ag	User
PreExistingConditions_FibrosisOfLung	Indication of patient showing symptoms of COVID-19 ● Yes ● No ● Unknown‡	No	Ig, Ag	User
PreExistingConditions_HeartFailure	Indication of patient showing symptoms of COVID-19 ● Yes ● No ● Unknown‡	Unknown	Ig, Ag	User
PreExistingConditions_HypertensiveDisorder	Indication of patient showing symptoms of COVID-19 ● Yes ● No ● Unknown‡	Yes	Ig, Ag	User
PreExistingConditions_Obesity	Indication of patient showing symptoms of COVID-19 ● Yes ● No ● Unknown‡	No	Ig, Ag	User
PreExistingConditions_PatientImmunocompromised	Indication of patient showing symptoms of COVID-19 ● Yes ● No Unknown‡	Unknown	Ig, Ag	User

* Indicates possible values

‡ Used as default if not changed by user

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Table 3. Used data fields (cont'd)

Fieldname	Description*	Example	Assay	Generated by
PreExistingConditions_Pregnant	Indication of patient showing symptoms of COVID-19 ● Yes ● No ● Unknown‡	Yes	Ig, Ag	User
PreExistingConditions_Rhabdomyoma	Indication of patient showing symptoms of COVID-19 ● Yes ● No ● Unknown‡	No	Ig, Ag	User
PreExistingConditions_SecondaryBacterialPneumonia	Indication of patient showing symptoms of COVID-19 ● Yes ● No ● Unknown‡	Unknown	Ig, Ag	User
PreExistingConditions_SickleCellDisease	Indication of patient showing symptoms of COVID-19 ● Yes ● No ● Unknown‡	Yes	Ig, Ag	User
PreExistingConditions_Smoker	Indication of patient showing symptoms of COVID-19 ● Yes ● No ● Unknown‡	No	Ig, Ag	User
PreExistingConditions_Thalassemia	Indication of patient showing symptoms of COVID-19 ● Yes ● No Unknown‡	Unknown	Ig, Ag	User

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‡ Used as default if not changed by user

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Table 3. Used data fields (cont'd)

Fieldname	Description*	Example	Assay	Generated by
PreExistingConditions_TraumaticInjuryOfSkeletalMuscle	Indication of patient showing symptoms of COVID-19 ● Yes ● No ● Unknown‡	Yes	Ig, Ag	User
Ethnicity	Ethnicity of patient ● AmericanIndian ● Arab ● BangladeshiPakistani ● Black ● Chinese ● HispanicLatino ● Indian ● White ● Mixed ● Other†	Chinese	Ig, Ag	User
Notes	Free text notes Maximum of 250 characters	Free text	All	User
eStick Batch Number	Batch number of eStick†	7432457	All	User
eHub Serial Number	Unique serial number of eHub	0030200608	All	System
eHub Software Version	Currently installed software version of eHub	1.07	All	System
QIAreach Software Version	QIAreach Software version used	1.2.0	All	System
ReasonForTesting_Contact/Exposure	Indication of reason for testing for LTBI ● Yes ● No ● Unknown‡	Yes	QIAreach QFT	User

* Indicates possible values

† Maximum of 25 characters

‡ Used as default if not changed by user

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Table 3. Used data fields (cont'd)

Fieldname	Description*	Example	Assay	Generated by
ReasonForTesting_MedicalRisk	Indication of reason for testing for LTBI ● Yes ● No ● Unknown‡	No	QIAreach QFT	User
ReasonForTesting_EpidemiologicalRisk	Indication of reason for testing for LTBI ● Yes ● No Unknown‡	Unknown	QIAreach QFT	User
ReasonForTesting_PatientRequest	Indication of reason for testing for LTBI ● Yes ● No ● Unknown‡	Unknown	QIAreach QFT	User
ReasonForTesting_Other	Indication of reason for testing for LTBI ● Yes ● No ● Unknown‡	No	QIAreach QFT	User

* Indicates possible values

‡ Used as default if not changed by user

Assay codings

Table 4 provides the LOINC and SNOMED codings for data elements in the CSV file. Use this table to identify and report test results in laboratory electronic reporting systems.

Table 4. Assay codings

Assay	Test types (LOINC)	Test types (non-LOINC)	Sample types (SNOMED)	Sample types (non-SNOMED)	Results SNOMED	Results (non-SNOMED)
QIAreach SARS-CoV-2 Antigen Test	94558-4	CoV2Ag	258500001^Nasopharyngealswab^SCT	Nasopharyngeal swab	260373001^Detected^SCT	Positive (+)
			445297001^Swabofinternal nose^SCT	Nasal swab	0415000^NotDetected^SCT	Negative (-)
QIAreach Anti-SARS-CoV-2 Total Test	Not applicable	Anti-CoV2	119364003^Serumspecimen^SCT	Serum	10828004^Positive^SCT	Positive (+)
			119361006^Plasmaspecimen^SCT	Plasma	260385009^Negative^SCT	Negative (-)

Document revision history

Date	Changes
December 2020	Initial release

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