Below is the flow chart for Lab mode. This includes the three use cases 1) Technician and Reader online, 2) Technician online but Reader offline and 3) Technician and Reader offline

Diagram

Description automatically generated

This workflow is easily adaptable for the at home mode where the technician is replaced by the patient. The assumption there is that the Patient and the Reader are both online and the user has an account already so there is not patient information collected.

Based on this, the following shows the screen mockups (mobile version) **(**Interactive desktop version at <https://invis.io/M410VKN3CNXF#/450908554_Desktop-Login>**)**

**Login Screen**

Graphical user interface, application, chat or text message

Description automatically generated

**Home Screen + User Menu**

Chart, funnel chart

Description automatically generated Chart, funnel chart

Description automatically generated

**Register Patient (Search)**

Graphical user interface, application

Description automatically generated Graphical user interface, text, application, chat or text message

Description automatically generated

**New Patient Entry**

Graphical user interface

Description automatically generated with medium confidence

**Associate Patient to Collector**

Graphical user interface, application

Description automatically generated Graphical user interface, application

Description automatically generated

**Test Result Search**

Graphical user interface, text, application, chat or text message

Description automatically generated Graphical user interface, application

Description automatically generated

**Test Result Details (Test Complete, Test Incomplete)**

Graphical user interface, text, application

Description automatically generated Graphical user interface, text, application

Description automatically generated

**Feature List**

Galen will create two an application and configure the Galen Cloud as described below for a Phase 1 prototype effort.

1. Aptitude Web Application (AWA) – Implementing the workflow as described in the diagram above.
   1. The AWA shall be designed to execute on an internet-based server.
   2. The AWA shall allow a lab technician to login to the Galen Cloud
      1. The AWA shall allow the lab technician to reset a forgotten password
   3. The AWA shall allow the lab technician to enter patient information for a new test
      1. First Name
      2. Middle Name
      3. Last Name
      4. Date of Birth
      5. Gender (Male, Female, Other, Declined to identify)
      6. Race (American Indian or Alaskan Native, Asian, Black or African American, Native Hawaiian or Pacific Islander, White, Other, Declined to identify)
      7. Ethnicity (Hispanic or Latino, Not Hispanic or Latino, Declined to identify)
      8. Email Address
      9. Phone Number
      10. Street Address 1
      11. Street Address 2
      12. City
      13. State
      14. Zip code
      15. Password
      16. Confirm Password
   4. The AWA shall allow the lab technician to associate a patient to a collector via entering or scanning a Collector Code (entered or scanned via a QR code)
   5. The AWA shall create a patient account (unless the account already exists) and save the patient + collector mapping in the Galen Cloud.
   6. The AWA shall allow the lab technician to enter or scan the reader and collector codes before the test run begins
      1. The AWA shall create the test entry (patient + collector + reader mapping) with status = Pending in the Galen Cloud
      2. The AWA shall create a notification when the test is started. Note: Notification are kept for that session only, once the user logs out or closes the browser, old notifications are no longer accessible
      3. When the notification is clicked, the AWA shall show the details of that test run (see item h below)
   7. The AWA shall allow the lab technician to search for test results associated with that lab/site
   8. The AWA shall allow the lab technician to view details on each test result
   9. The AWA shall allow the lab technician to manually update the test results if the result is not already set (test not completed).
      1. The AWA shall allow the lab technician to upload a photo (png or jpeg) associated with the test during manual upload
      2. The AWA shall save the test results and mark the test as Completed
   10. The AWA shall allow the lab technician to bulk insert test information from a CSV file
       1. The AWA shall require a compatible CSV file to be uploaded
       2. For each test information in the CSV file the AWA shall
          1. Create patient account (if needed)
          2. Create the test record (patient + collector + reader + test results)
   11. The AWA shall allow the lab technician to update their own profile and password

Galen Cloud functions (Included as part of the effort) as described in the diagram above.

1. Notification (Email, SMS) to patients upon completion of test

Reader function (blue boxes in the diagram above) are **NOT** included in this effort and will be responsibility of Aptitude) including but not limited to

1. The Reader software shall poll the Galen Cloud for a pending test record using its reader identifier
2. The Reader software shall use the test record identifier to send results
3. The Reader software shall indicate an error if the no such record exists
4. The Reader software shall indicate an error if the reader is offline
5. Creation and management of the Wi-Fi network functionality for the Reader

# Data Structure Definition

**Data Model: Test Information** - Scope: Patient (Patient info is auto captured by Galen Cloud)

|  |  |  |  |
| --- | --- | --- | --- |
| **Name** | **Type** | **Prop Code** | **Description** |
| Collector Id (Unique) | Text | CollectorId | Identification of the Collector |
| Reader Id | Text | ReaderId | Identification of the Reader |
| Sample Collected On | Date and Time | SampleCollectedOn | The date and time the sample was collected (the time the patient was associated with the collector) |
| Sample Collected By | Text | SampleCollectedBy | The identifier of the user collecting the sample |
| Test Run By | Text | TestRunBy | The identifier of the user doing the test |
| Test Start Date | Date and Time | TestStartDate | The date and time the test was started. This is going to be the same as "Assigned To Reader", but could diverge in future |
| Test End Date | Date and Time | TestEndDate | The date and time the test was ended. |
| Test Complete | Yes/No | TestComplete | A flag to indicate if the test is complete or not |
| Test Result | Text | TestResult | The result (positive, negative, invalid) of the test |
| Test Photo | Image | TestPhoto | Image of the test results (LED lights e.g.) |

**Data Model: Reader List –** Scope: Practice(Site (Practice) Info is auto captured by Galen Cloud)

|  |  |  |  |
| --- | --- | --- | --- |
| **Name** | **Type** | **Prop Code** | **Description** |
| Reader Id (Unique) | Text | ReaderId | Identification of the Reader |
| Created on | Date and Time | CreatedOn | The date and time the reader was created in the system |
| Heartbeat Received On | Date and Time | HeartbeatReceivedOn | The date and time the last heartbeat was received on |
| Status | Text | Status | Error or other status |

**Data Model: Reader Raw Data** – Scope: Manufacturer

|  |  |  |  |
| --- | --- | --- | --- |
| **Name** | **Type** | **Prop Code** | **Description** |
| Reader Id | Text | ReaderId | Identification of the Reader |
| Collector Id | Text | CollectorId | Identification of the Collector on which this test was run. |
| Test Date | Date and Time | TestDate | The date and time the test was run on reader |
| Measurement | JSON | Measurement | The raw measurements from the reader |
| Temperature | JSON | Temperature | The temperature values from the reader |
| Fluid Fill | JSON | FluidFill | The fluid fill values from the reader |
| Curve Fit | JSON | CurveFit | The curve fit values from the reader |
| Result QC | Text | ResultQc | The quality control text |
| Firmware Version | Text | FirmwareVersion | The firmware version of the reader |

# API

Base URL: <https://api.galencloud.com>

Headers:

X-TENANT-DOMAIN: aptitudedev.galencloud.com (needs to be configurable for production)

X-API-VERSION: 3

X-APP-TYPE: Device

|  |  |  |  |
| --- | --- | --- | --- |
| **Function** | **Component** | **API** | **Request Body / Params** |
| Login | Reader / Web App | POST /auth/login |  |
| Create Practice | Reader | POST /user/practice |  |
| Create Patient | Reader / Web App | POST /user/user |  |
| Assign Patient to Collector | Web App | POST /data/devicedata |  |
| Assign Collector to Test | Web App | POST /data/devicedata |  |
| Get Test for Collector | Web App | GET /data/devicedata-advanced/user |  |
| Get Reader (for verification of id) | Web App | GET /data/devicedata-advanced |  |
| Get Pending Test for Reader | Reader | GET /data/devicedata-advanced |  |
| Set Test Results | Reader / Web App | POST /data/devicedata |  |
| Send Raw Data | Reader | POST /data/devicedata |  |
| Login | Web App | POST /auth/login |  |
| Send Heartbeat | Reader | POST /data/devicedata-advanced |  |

# Branding Guidelines

1. Fonts: Open Sans for body, and Lato for Headings
2. Colors
   1. Primary: Blue (#368AB6)
   2. Accent 1: Light Gray (#D1D3D4)
   3. Accent 2: Dark Gray (#2A2A2A)