Calibrator and Control Management Software

Purpose

1. To document the specifications and use of calibrators and controls.
2. To ensure, by means of workflow and label scanning, that that only valid, correct controls and calibrators are used for each antigen plate.
3. To provide reporting capability of the control and calibrator information captured in the software

# Platform

The software will be written as a desktop application in WPF. All data will reside on a local server. Database will be SQL Express.

# Software Startup Landing Page/Login Screen

**Username** is the email entered on the User Admin page

**Password** is their current password

## LOGIN BUTTON FUNCTION

If a username is valid and enabled, and the password is correct, then:

1. If the user logs in using a temporary password created by an admin, then they are taken to the **password reset page** to create their own unique password.
2. If the user logs in with their own user created password, then they are taken to the **logged in landing page**.
3. The log-in landing page for NON-ADMIN should be the “Assign Calibrators and Controls” page.
4. The log-in landing page for an ADMIN should be “Manage Users” page.

If a username is either invalid or disabled, give the message, “Invalid User.”

If a username is valid and enabled, and the password is incorrect, give the message, “The username and password do not match.”

# User Management – ADMIN ONLY

**Path:** Admin>Users

1. Landing page displays a list of users.
2. **“View”** settings. There are three View Settings. They determine which users are displayed in the User List Window:
   1. Active Users displays only active users. Default view is set to “Active Users.”
   2. Disabled Users displays only Disabled Users.
   3. All Users displays all users.
3. “**Find User**” search field. User may enter a part of a user’s information (first name, last name, email). When the search icon is clicked, show the search results in the User List Window. *The “View” settings still apply*.
4. **“+ Add User”** If selected, user will be taken to the “Add User” page.
5. **“Export to Excel”** All user data in the User List Window will be exported to an Excel file, or CSV file. NOT A CRITICAL REQUIREMENT FOR LAUNCH.

## Table Fields

1. **User ID** This is a sequentially generated and applied GUID for the users. The software should create this. It is not user assignable. It begins with “1”. Once a user ID is created, it may never be reused, even if the user is deleted.
2. **First Name**
3. **Last Name**
4. **Email** This is a required field and is the Username used to log-in to the software
5. **Admin** If checked, the user is assigned admin role privileges. There must always be one admin registered in the system. The last admin may not change themselves to a user unless another user is assigned as an admin. If the last admin tries to change to a user, give the message, “Error. At least one admin is required.”
6. **Disable** Disabled users are prevented from logging into the software. If a user is logged in when their user account is disabled, they will be immediately logged out.

## Add User Page

**Path:** Admin>Add Users OR from the User Management Page “+ Add User”

1. **First Name** Limit 25 characters
2. **Last Name** Limit 25 characters
3. **Email**
   1. This is their username to log-in to the software
   2. Limit 50 characters
4. **ReEnter Email** Confirm that the addresses are the same when leaving field
5. **Temporary Password** 
   1. This field should remain visible text. Limit to 25 characters.
   2. **REQUIREMENT:** Password should be minimum six characters and include both letters and numbers. This is the same requirement for the user created password.
6. **USER/ADMIN**
   1. These are radio buttons.
   2. “User” is default selected
   3. If “Admin” is selected and saved, user is granted Admin user role rights.

## Editing a User

To edit a user, double click on a user when visible in the User List Window. This will open the user in the **“Edit User”** window, with all of the User’s data populated in the fields. Temporary Password will be blank.

If any data in the field is edited and saved, it will change the information on the User’s account.

If a Temporary Password is entered and saved, it will reset the User’s Password and will require the user to reset their password upon next log-in using the reset temporary password. If the user whose password is reset is currently logged in, they will be immediately logged out of the system when their password is reset.

There must always be one admin registered in the system. The last admin may not change themselves to a user unless another user is assigned as an admin. If the last admin tries to change to a user, give the message, “Error. At least one admin is required.”

# Creating a Calibrator or Positive Control

**Path:** Create>Calibrator OR Create>Pos Control

1. **Array** ONLY MASTER ARRAYS may be selected here. User may type in this field, or select the drop down. If they type, the field will act as a search and show items from the list that apply. User must select from the list the Array that they want. The list contains all MASTER Arrays currently active in the C&C Software.
2. **Antigen Group** There are six possible groups. Create a drop-down list numbered 1-6.
3. **Antigen** This should be a drop down that contains the list of antigens in the selected group. They must select one from the list.
   1. Antigens should always be listed by their **number** first, and then their name
4. **Serum Reference** The user will add here the accession numbers of the serums used in the creation of the calibrator. The information may be scanned from the serum bar code or hand entered.
   1. This is a text field with a maximum of 30 characters.
   2. After the serum reference number is entered, the user must select “ADD” or the Green + icon, to add the reference number. Reference numbers that have been added will be listed under the input box.
   3. A red “-“ icon will show next to each reference number. If selected, it will remove the serum reference number from the list.
   4. Multiple serum reference numbers may be added, one at a time. They will all show as a list below the serum reference number field.
5. **Dilution Factor** This will be a number to a maximum of five digits.
6. **Dilution Date** This is a date field. Have a calendar drop down that allows a date select. The calendar should open defaulted to the current month.
7. **Expiration** This is a date field that will automatically populate once the dilution date field is entered. Once populated it remains editable by the user.
   1. **Expiration Date Formula** The expiration date is on the end of the 90th calendar day from the dilution date.
      1. Example 1: For a dilution date of March 1, the expiration date will be on May 30 at 23:59.59
      2. Example 2: For a dilution date of March 15, the expiration date will be on June 13 at 23:59.59.
8. **Min & Max fields** These are number fields. They must handle decimals. Max 10 digits.
9. **Lot Number** The Lot Number is automatically generated by the software once the dilution date has been entered.
   1. The Lot number specifications are: Where P is for pos control, N is for a neg control, C is for a calibrator: A[array #][P/N/C][antigen #]-[dilution date in MMDDYYYY]
   2. Example 1: Array 3X antigen 1 Wheat, calibrator diluted on 12/13/19 would be   
      A3XC1-12132019
   3. Example 2: Array 8, antigen 3 NPA, positive control diluted on 1/3/20 would be   
      A5P3-01032020
10. **Qty Labels to Print** This is a number field. The number that is entered here determines the number of barcode labels that will print when the Calibrator is saved.
    1. **Barcode Label** The label will have the lot number in a barcode format (same label as the LIM accessioning label). In addition to the bar code, the following should be listed in text under the bar code:
       1. Lot number in barcode format
       2. Lot number as text
       3. Expiration Date as text
       4. Antigen name and plate number. IF NEG CONTROL, then instead of antigen name and plate number, write UNIV
    2. EXAMPLE:
    3. Label Size to be supplied
11. **Save** 
    1. All fields above are required. If any are blank, highlight the missing data field in red and provide an error message, “please complete all data.” At least one Serum Reference number is required.
    2. If Save is selected, and all data fields are completed, the calibrator is saved and the form field resets all fields.
12. **Save and Next** If this button is selected, the calibrator is saved and then:
    1. **Array** remains the same. All other fields except Antigen Group clear.
    2. **Antigen Group**
       1. If the calibrator just saved was not the last in the antigen in the group, then the antigen group remains the same
       2. If the calibrator just saved was the last antigen in the group:
          1. If there is another group in the Array, go the next group
          2. If there are no more groups:
             1. Give message: “That was the last antigen in the Array list.” Provide “OK” button.
             2. When “OK” is selected, the calibrator is saved and the form field resets all fields.
13. **Exit Without Saving** Clears all data entered into the form fields and system returns to the default log-in window.

# Creating a Negative Control

**Path:** Create>Neg Control

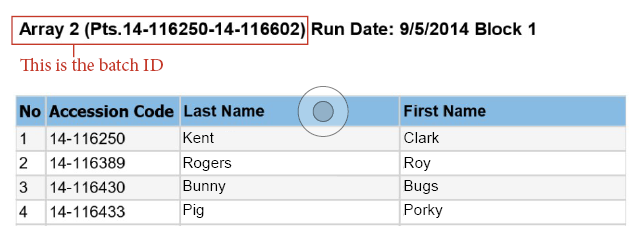
Negative controls, unlike positive controls and calibrators, are often shared across all antigens within an Array. However, while the negative control itself is the same, the min/max data for each antigen is different. The UI for creating and assigning negative controls is therefore unique.

1. **Array** ONLY MASTER ARRAYS may be selected here. User may type in this field, or select the drop down. If they type, the field will act as a search and show items from the list that apply. User must select from the list the Array that they want. The list contains all MASTER Arrays currently active in the C&C Software.
2. **Antigen Group** There are six possible groups. Create a drop-down list numbered 1-6. 
   1. Once the Antigen group number is selected, display all the antigens in that group in the display window. Antigens should always be listed by their **number** first, and then their name.
3. **Serum Reference** The user will add here the accession numbers of the serums used in the creation of the calibrator. The information may be scanned from the serum bar code or hand entered.
   1. This is a text field with a maximum of 30 characters.
   2. After the serum reference number is entered, the user must select “ADD” or the Green + icon, to add the reference number. Reference numbers that have been added will be listed under the input box.
   3. A red “-“ icon will show next to each reference number. If selected, it will remove the serum reference number from the list.
   4. Multiple serum reference numbers may be added, one at a time. They will all show as a list below the serum reference number field.
4. **Dilution Factor** This will be a number to a maximum of five digits.
5. **Dilution Date** This is a date field. Have a calendar drop down that allows a date select. The calendar should open defaulted to the current month.
6. **Expiration** This is a date field that will automatically populate once the dilution date field is entered. Once populated it remains editable by the user.
   1. **Expiration Date Formula** The expiration date is on the end of the 90th calendar day from the dilution date.
      1. Example 1: For a dilution date of March 1, the expiration date will be on May 30 at 23:59.59
      2. Example 2: For a dilution date of March 15, the expiration date will be on June 13 at 23:59.59.
7. **Lot Number** The Lot Number is automatically generated by the software once the dilution date has been entered.
   1. The Lot number specifications are: Where P is for pos control, N is for a neg control, C is for a calibrator: A[array #][P/N/C][antigen #]-[dilution date in MMDDYYYY] IF A NEG CONTROL IS ASSIGNED TO A SINGLE ANTIGEN ONLY (MEANING THERE ARE MIN/MAX FIELDS FOR ONLY ONE ANTIGEN TOTAL) THEN THE LOT NUMBER WILL CONTAIN THE ANTIGEN NUMBER LIKE A NORMAL LOT NUMBER. IF THE NEG CONTROL IS ASSINGED TO MORE THAN ONE ANTIGEN, THEN THE LOT NUMBER WILL OMIT THE ANTIGEN NUMBER. FOR EXAMPLE, INSTEAD OF A3XN3-12132019, A UNIVERSAL LOT WOULD BE A3XN-12132019. **Tom, see ID UI for additional field, “APPLY ANTIGENSN TO EXISTING NEGATIVE CONTROL”**
   2. Example 1: Array 3X antigen 1 Wheat, calibrator diluted on 12/13/19 would be   
      A3XC1-12132019
   3. Example 2: Array 8, antigen 3 NPA, positive control diluted on 1/3/20 would be   
      A5P3-01032020
8. **Qty Labels to Print** This is a number field. The number that is entered here determines the number of barcode labels that will print when the Calibrator is saved.
   1. **Barcode Label** The label will have the lot number in a barcode format (same label as the LIM accessioning label). In addition to the bar code, the following should be listed in text under the bar code:
      1. Lot number in barcode format
      2. Lot number as text
      3. Expiration Date as text
      4. Antigen name and plate number. IF NEG CONTROL, then instead of antigen name and plate number, write UNIV
   2. EXAMPLE:
   3. Label Size to be supplied
9. **Min & Max fields** 
   1. These are entered individually for each antigen in the group directly in the display window to the right. These are number fields. They must handle decimals. Max 10 digits.
   2. When tab is selected, the curser should move from left to right (min to max) and then down. So, Min<tab>Max on same line<tab>Min on next line down<tab>Max on same line, etc.
10. **Save** 
    1. Required fields to save.
       1. Array, Antigen Group, at least one Serum reference number, Dilution factor, Dilution Date, Exp Date, Lot Number, Label Qty (can be “zero”), and at least ONE antigen with min/max data.
          1. If any fields, other than the min/max fields are blank, highlight the missing data field in red and provide an error message, “please complete all data.”
          2. If at least one antigen does not have min/max data, provide the error message, “At least one antigen must have min/max data.”
          3. If either a min or max field has data, the corresponding min/max field must also have data. If only one is populated, give the error message…
    2. If Save is selected, and all data fields are completed, the calibrator is saved and the form field resets all fields.
11. **Save and Next** If this button is selected, the calibrator is saved and then:
    1. **All fields in Create window, except the Antigen Group data and label QTY, maintain their data** (Array, Serum Reference Number, Dilution factor, Dilution Date, Exp Date, Lot number) remains the same.
    2. **Antigen Group**
       1. If there is another antigen group with antigens in it after the current one just saved,
          1. **All fields in Create window, except the Antigen Group data and label QTY, maintain their data** (Array, Serum Reference Number, Dilution factor, Dilution Date, Exp Date, Lot number) remains the same.
          2. Move to the next antigen group with antigens in it (2 moves to 3, 3 moves to 4, etc) and populate the window with the new antigen list.
          3. Clear label QTY field. This should be entered each time.
       2. If the antigen group just saved was the last antigen group (there are no additional groups with antigens, or this was group number 6):
          1. Give message: “That was the last antigen group.” Provide “OK” button.
          2. When “OK” is selected, the negative control is saved and the form field resets all fields.
12. **Exit Without Saving** Clears all data entered into the form fields and system returns to the default log-in window.

# Assign Calibrators and Controls

**Path:** Assign>Assign C&Cs

1. There is a 2D (QR) barcode on the batch sheet the user will be using. The barcode is formatted as follows using HL7 style delimiters:
   1. |Array Number | First patient in range | Last Patient in range| Run Date MM/DD/YEAR| Block number|
      1. QR code sample:  
          
      2. Data Readout from Sample QR Code scan:   
         |6|14-116250|14-116602|10/12/2020|1|
   2. The user will scan this 2D barcode. The software will parse the 2D data and will automatically fill the following fields:
      1. **Batch ID is created from data and formatted as follows (see sample batch sheet header below):  
         Array [# or name] (Pts. [first]-[last])**
      2. **Run Date**
      3. **Block Number**

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1. **Antigen Group** There are six possible groups. Create a drop-down list numbered 1-6. 
   1. Once the Antigen group number is selected, display all the antigens in that group in the display window. Antigens should always be listed by their **number** first, and then their name
   2. Antigens should be listed in three columns
      1. Calibrators
      2. Negative Controls
      3. Positive Controls
   3. Each column will list the antigens in that group by number and name in order of the number. Next to each antigen should be a Lot number field where the lot number can be scanned or entered.
   4. TAB MOVEMENT: Tab should move DOWN the columns, first. When they reach the bottom field in a column, they then move to the top of the next column with the exception as follows.
      1. At the top of the Negative Control column there is a lot number data field with a check box that reads, “Use For All”.
      2. When tab is pressed from the last data field in the first column, it should go to the “use for all” lot data field. AFTER THAT, it should NOT go down, but across to the top of the positive control list, and then down that list.
      3. If the cursor is placed in any of the individual lot number fields in the neg control field, and then tab is pressed, it would then move down the neg control list. Upon reaching the bottom of the Pos Control, Tab will move to the top of the Pos Control.
      4. When the cursor reaches the bottom of the Positive Control, TAB moves the selector to the “Save and Next” button.
2. **Allow Partial Antigens**.
   1. If this box is checked, it allows data to be saved if not all the antigens have data.
   2. Regardless of whether the box is checked, if any antigen has data in any of the columns, it is required to have data in all the columns.
      1. For example, if antigen 1 has a lot number in the calibrator column, it is required to have lot numbers in the neg control and pos control columns as well.
   3. If this box is not checked, every lot number must be populated.
3. **Entering Data**
   1. The user, after scanning the QR code to identify the batch and selecting the antigen group, will scan (or hand enter) the lot information into each field.
   2. CALIBRATORS
      1. They will start in the first Calibrator lot field, and scan the barcode from the calibrator lot.
      2. They will press tab to move down to the next lot field, scan the next lot, and press tab again, and so forth.
   3. NEG CONTROLS
      1. Negative controls are almost always universal (the same for all antigens). Therefore, the cursor will automatically populate the top lot number field with the check box “apply to all”
      2. When apply to all is selected, the lot number in the top lot field is written into all of the lot numbers in the Neg Control column. If there is data already present in any of the fields when “Apply to All” is selected, it will overwrite the data.
      3. Once the lot data has been applied, clear the “Apply to All” lot data field.
      4. Data that has been written into a neg control lot field by using the Apply to All button remains editable and can be modified individually after being applied.
   4. POS CONTROLS
      1. They will start in the first Pos Control lot field and scan the barcode from the calibrator lot.
      2. They will press tab to move down to the next lot field, scan the next lot, and press tab again, and so forth.
      3. When the last Pos Control lot field is reached, and tab is selected, move the cursor to “Save and Next”
4. **Save** 
   1. Required fields to save.
      1. Batch ID, Run Date, Block Number, Antigen Group
      2. If the “Allow Partial Data” box is not checked, then all the lot data fields must be populated.
   2. DATA CHECK AND CONFIRMATION
      1. Every lot data field is checked against the database to confirm that it is correct.
      2. The following QC check is performed to ensure that lot numbers have been correctly applied:
         1. Does the lot number exist as an active lot?
            1. Yes. Proceed.
            2. No. Fail. Capture failure and move to next.
         2. Is the lot number applied to the correct antigen?
            1. Yes. Proceed.
            2. No. Fail. Capture failure and move to next.
         3. Is the lot number expired?
            1. Yes. FAIL. Capture failure and move to next.
            2. No. Proceed.
      3. If any QC checks failed, DO NOT SAVE. Keep window open and all data populated.
         1. Provide error message: “Error. Lot(s) highlighted in red have failed.”
         2. Highlight in RED all lot numbers that failed the QC check.
         3. User must correct those lot numbers and try to save again. Each time they try to save, the QC check is performed. Data will only save if all data passes the QC check.
      4. If all QC checks pass, save the data.
         1. The neg control “Apply to All” lot number field is not saved. It is a temporary data field only used for the Apply to All function. It is not required to have data in it when saving.
5. **Save and Next** If this button is selected, the calibrator goes through the save process above. Once data is saved, then:
   1. If there is subsequent antigen group with antigens in it after the current one just saved,
      1. **All data in Batch ID, Run Date and Block Number remain the same**.
      2. Move to the next antigen group with antigens in it (2 moves to 3, 3 moves to 4, etc) and populate the window with the new antigen list.
      3. All lot number fields clear.
   2. If the antigen group just saved was the last antigen group (there are no additional groups with antigens, or this was group number 6):
      1. Give message: “That was the last antigen group.” Provide “OK” button.
      2. When “OK” is selected, clear all fields.
6. **Exit Without Saving** Clears all data entered into the form fields and system returns to the default log-in window.