



HORIBA Quality Control Program

HMUS Web QC User Manual V1.2

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Contents

1- Introduction	
1.1 – Terms and Conditions	3
1.2 – Limited Guarantee	6
1.3 – Updates	6
1.4 – Acronyms	6
2 – Website Design Overview	7
3 – Web User Interface and Description	9
3.1 – Home Screen	9
3.2 – Login Screen	10
3.3 – Forgot Your Password Screens	11
3.4 – Enroll Screen	13
3.5 – Contact Us Screen	14
3.6 – Dashboard Screen	15
3.6.1 – Quality Control Information	16
3.6.2 – Quality Control Calculations	19
3.6.3 – QC Lot Details Report	23
3.6.4 – Levey Jennings Chart Report	25
3.6.5 – Performance Index Report	27
3.7 – +Uploads Menu and Screens	29
3.8 – Downloads Screen	31
3.9 – +Account Settings Menu and Screens	32
3.9.1 – Facility/Instruments Screen	32
3.9.2 – Users Screen	34
3.9.3 – Notifications Screen	35
3.9.4 – Facility Westgard Settings Screen	35
3.10 – Contact Us Screen	35
3.11 – Logout	36
3.12 – My Profile Screen	36
3.13 – Help Screen	37

1. Introduction

1.1 - Terms and Conditions

The Quality Control Program service referred to as "Web QC" is owned and operated by HORIBA Instruments Incorporated dba HORIBA Medical, a California corporation with its principal office at 9755 Research Drive Irvine, California CA 92618 USA, hereinafter referred to as the "HORIBA".

HORIBA provides the content on this Web Site subject to the following Terms and Conditions, that apply to everyone who accesses and uses this Site, to all content available under the domain name "rt.qchoriba.com", hereafter referred to as the "Site", or "Web QC" or any domain name alias to the same content.

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- **Definitions**

"Services" means any functions, facilities, applications, information or other services available through this Site.

"User" means any person who accesses or uses this Site with or without HORIBA's authorization and whether or not they are registered to use any part of this Site, a member or registered User of a Service offered through this Site.

"Statistical Reports" means any statistical processing of values that have been submitted by the User to Web QC via manual input of daily results, summary results or via transmission with CSV files, XML files, and that are made available to the User through the Site.

"Site" means the HORIBA (Quality Control Program) or other collection of information and/or applications operated by HORIBA.

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User may not otherwise reproduce, modify, distribute, transmit, post, or disclose the Site content without HORIBA's written prior consent.

User shall not use WEB QC or the Services in a way that breaches these Terms and Conditions or any applicable law or regulations or that causes or is likely to cause any damage, interruption or impairment of this Site, or the Services. User may not attempt to gain unauthorized access to any part of this Site, other User accounts or any computer systems or networks connected to this Site, whether through hacking, password mining or any other means. User may not collect or attempt to collect personal information relating to others through the Site.

- **User Registration**

To post, upload or download materials, communicate via and to access Web QC, Services, resources and all Site content, User may be asked to provide registration details and log on. It is a condition of use of this Site, Services, and Web QC content that all registration details User provides are and will remain true, correct, current, and complete.

User agrees to use the online forms in the Web QC website to notify the HORIBA immediately of any changes which are relevant to this registration.

If the HORIBA believes the details are not correct, current, or complete, or if HORIBA otherwise in its discretion believes such action would be appropriate, including where it suspects the registration of multiple account or User profiles by the same individual, it has the right to refuse User's access to Web QC, and/or any of its resources, Services and content, and to terminate or suspend User's account.

- **User Postings**

User represents and warrants that all information, regarding the quality control results issued by HORIBA's instruments, that he submits is true and accurate, and that HORIBA instruments are used with HORIBA reagent and control and consumable product only and as per the HORIBA's instructions to users.

User acknowledges, agrees and guarantees that HORIBA shall own and have the unrestricted right to use, publish, and otherwise exploit any and all information that User posts or otherwise publishes on the Site.

- **Personal access**

Only Users duly registered have been authorized by HORIBA may have access to the restricted area of the Site.

Users are entirely responsible for maintaining the confidentiality of your password and account. Furthermore, you are entirely responsible for any and all activities that occur under your account. You agree to notify HORIBA immediately of any unauthorized use of your account or any other breach of security here. HORIBA will not be liable for any loss that you may incur as a result of someone else using your password or account, either with or without your knowledge. However, you could be held liable for losses incurred by

HORIBA or another party due to someone else using your account or password. You may not use anyone else's account at any time, without the permission of the account holder.

You may not attempt to gain unauthorized access to any Web Site or Material, other accounts, computer systems or networks connected to any HORIBA server or Materials, through hacking, password mining or any other means or obtain or attempt to obtain any materials or information through any means not intentionally made available through the Web Sites or Materials;

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- **Governing law and jurisdiction**

The Terms and the relationship between you and HORIBA shall be governed by the laws of the State of California, USA without regard to its conflict of law provisions and each party shall submit to the personal and exclusive jurisdiction of the courts located within the State. If any provision of these Terms is found by a court of competent jurisdiction to be invalid, the parties nevertheless agree that the court should endeavor to give effect to the parties' intentions as reflected in the provision, and the other provisions of the Terms remain in full force and effect.

1.2 - Limited Guarantee

The duration of guarantee is stipulated in the Sales conditions associated with the purchase of this system. To validate the guarantee, ensure the following is adhered to:

- The system is operated under the instructions of this manual.
- Only software or hardware specified by HORIBA Medical is installed on the system. This software must be the original copyrighted version.
- Services and repairs are provided by a HORIBA Medical authorized technician, using only HORIBA Medical approved spare parts.
- The electrical supply of the laboratory adheres to national or international regulations.
- The system is operated according to HORIBA Medical recommendations.

All peripheral devices should comply with relevant standards.

If this system has been supplied to you by anyone other than HORIBA Medical or an authorized representative, HORIBA Medical cannot guarantee this product in terms of specification, latest revision and latest documentation. Further information may be obtained from your authorized representative.

1.3 – Updates

V1.0 – Initial Release

V1.1 – Added result upload, selectable date range, result search and comment features, QC Lot Details report, PI and LJ report improvements, Contact US improvements

V1.2 - Modified manual entry instructions to correspond with Site enhancements

1.4 – Acronyms

Acronym	Description
HMUS	HORIBA Medical United States
Site	HMUS-QC Website
QC	Quality Control
RT	Real Time
QC-RT	Quality Control Real Time
SID	Sample Identification Number
LIS	Laboratory Information System
UI	User Interface
URL	Uniform Resource Locator (web address)

2 - Website Design Overview

- HMUS QC Web is designed to be responsive, allowing users to access the Site via any connected device; PC, Tablet, Phone and with minimal user interface differences. Although the responsive design is implemented, the experience may vary drastically on a small screen device depending on the amount of data being presented.
- The Site Components consist of (Figure 1)
 - User Interface:
 - Account / Facility Structure allows one Account to be created for multiple associated Facilities and multiple instruments to be assigned to a single facility while allowing the Account User to still see all Account and Facility information. This structure allows for peer evaluation at the Account, Facility and Site levels
 - The Site access structure (Figure 2) has 3 authority levels and depending on the authority level of the user, the user has access to additional functionality of the Site
 - HORIBA Administrator – full Site access
 - Account User/Owner – access to created account information and the ability to create / edit / view any and all users, facility(s), and instrument(s) created under this account (Figure 3)
 - Facility User – Only has access to the facilities and instruments for the account for which they have been assigned by the Account Owner (Figure 4)
 - WebService
 - API designed to allow communication with and transmission of QC data to The Site
 - Parses received transmissions and stores this information in the database and file storage
 - File Storage
 - Storage of API requests
 - Monthly Reports generated
 - Database
 - Relational database model used to store site data as well as QC transmissions

Figure 1: Site Components

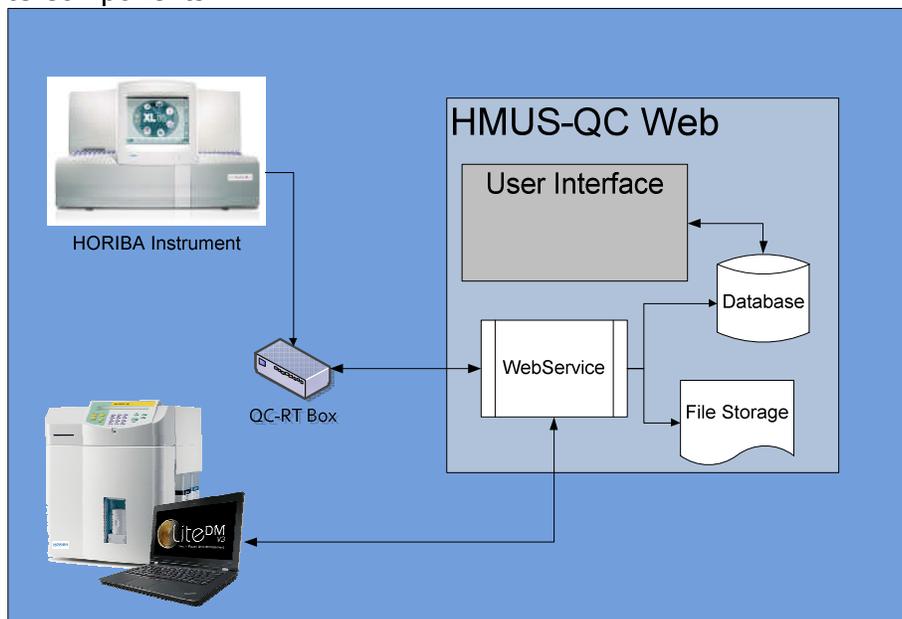


Figure 2: User structure

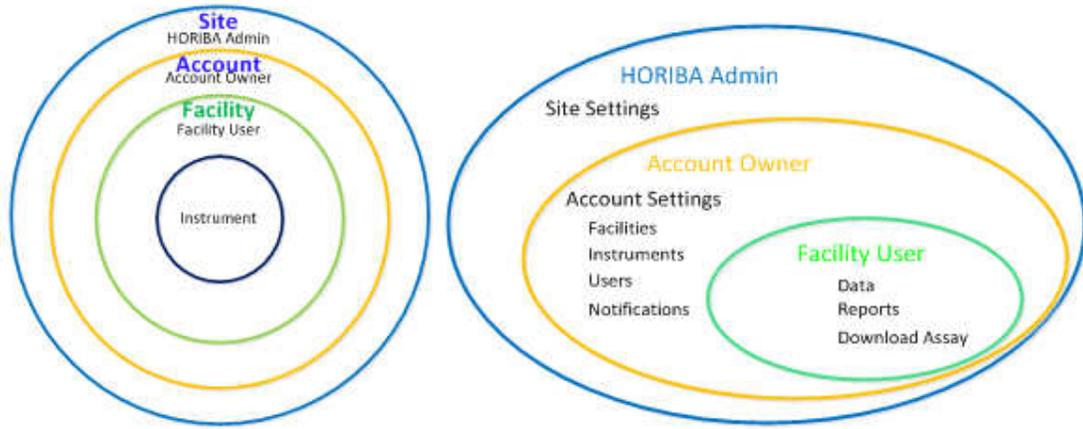


Figure 3: Account User access

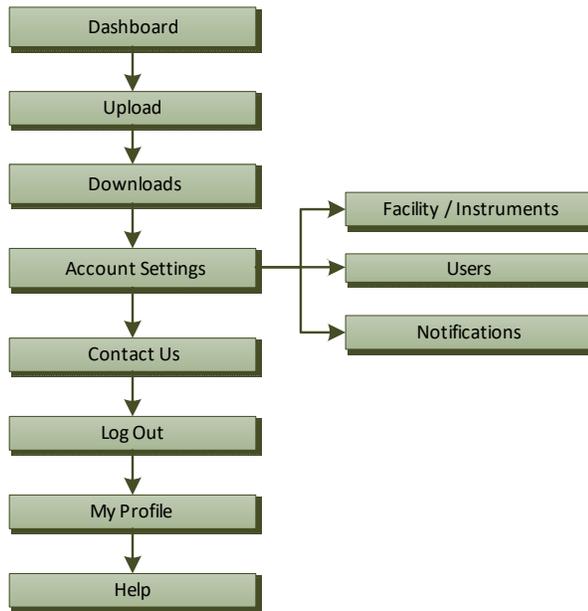
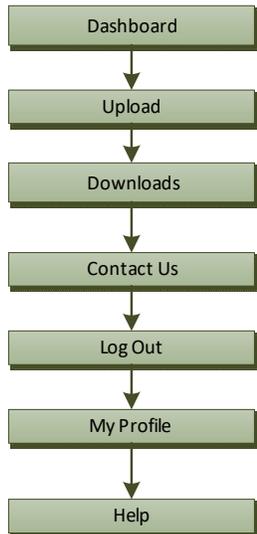


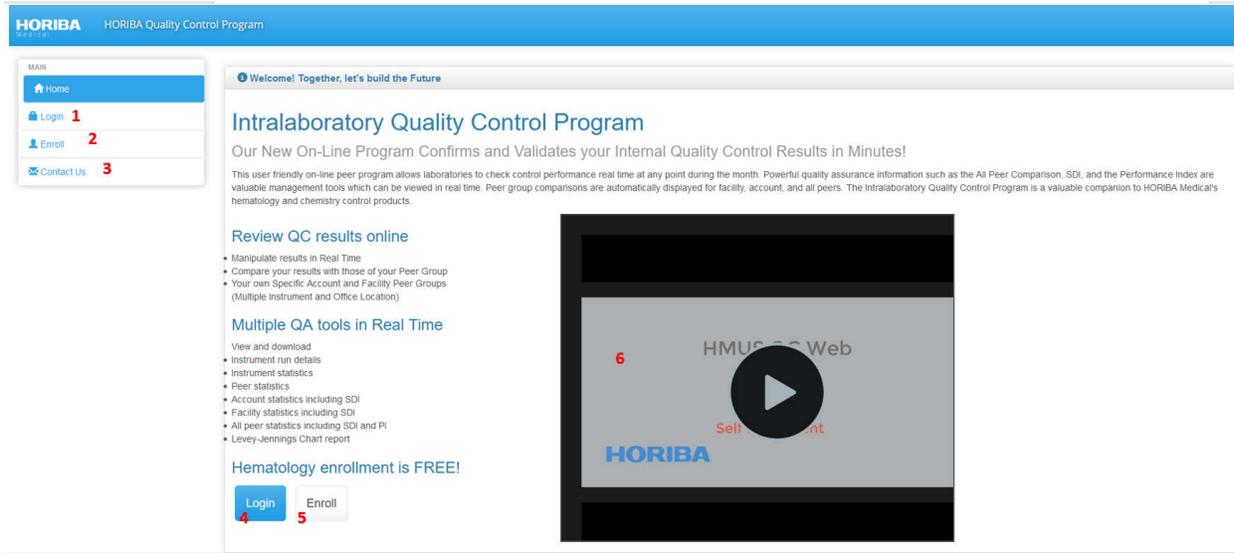
Figure 4: Facility User access



3 - Web User Interface and Description

Home Screen

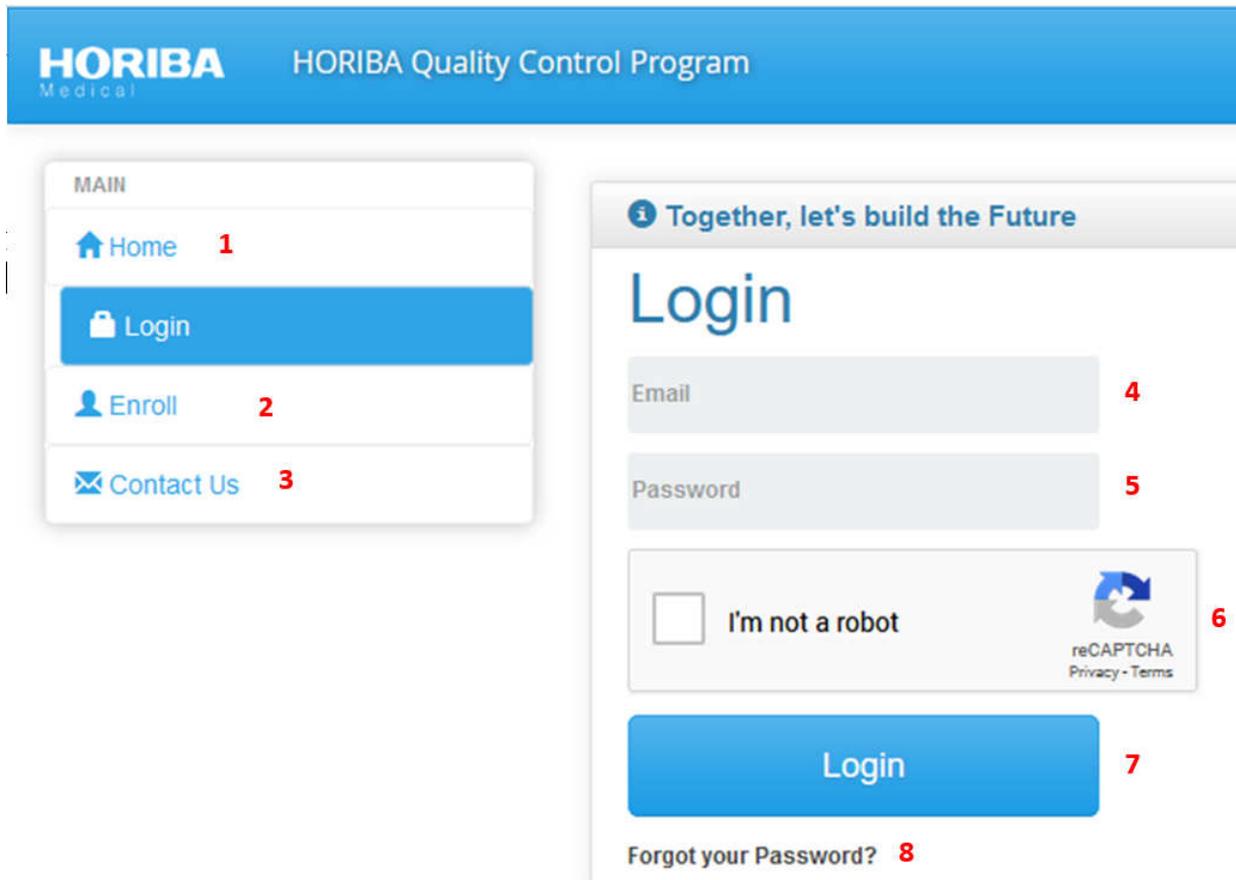
- URL: <http://rt.qchoriba.com/home>
- Displays general information about the site and allows user to navigate to Login, Enroll, or Contact Us (HMUS)



#	Item	Type	Description
1	Login	Navigation	Navigates to Login screen
2	Enroll	Navigation	Navigates to Enrollment screen
3	Contact Us	Navigation	Navigates to Contact Us screen
4	Login	Button	Navigates to Login screen
5	Enroll	Button	Navigates to Enrollment screen
6	Video	Video Player	Enrollment video (no narration)

Login Screen

- Allows user to input email address and password for access
- User has link to Forgot your Password screen to perform password reset
- User has navigation to Home, Enroll, and Contact Us screens

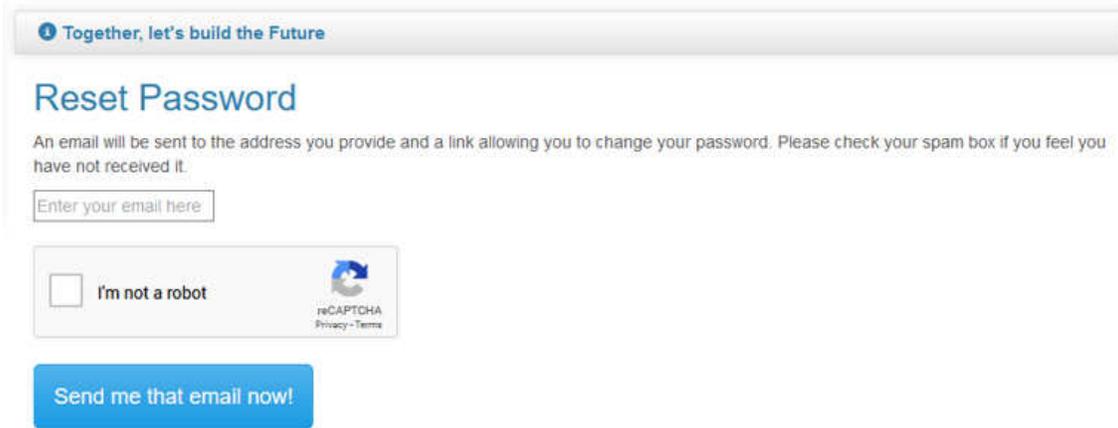


#	Item	Type	Description
1	Home	Navigation	Navigates to Home screen
2	Enroll	Navigation	Navigates to Enrollment screen
3	Contact Us	Navigation	Navigates to Contact Us screen
4	Email	Email Field	Email address of site user
5	Password	Password Field	Password of site user
6	reCAPTCHA	Web security tool	Security to prevent abusive traffic to the site https://www.google.com/recaptcha/intro/v3.html
7	Login	Link	Valid user email and password allows access to the site.
8	Forgot your Password	Navigation	Navigates to password reset screen

- User enters email address, password, completes the reCAPTCHA requirement, and selects the "Login" button
- User is allowed access to the site and is directed to the Dashboard screen

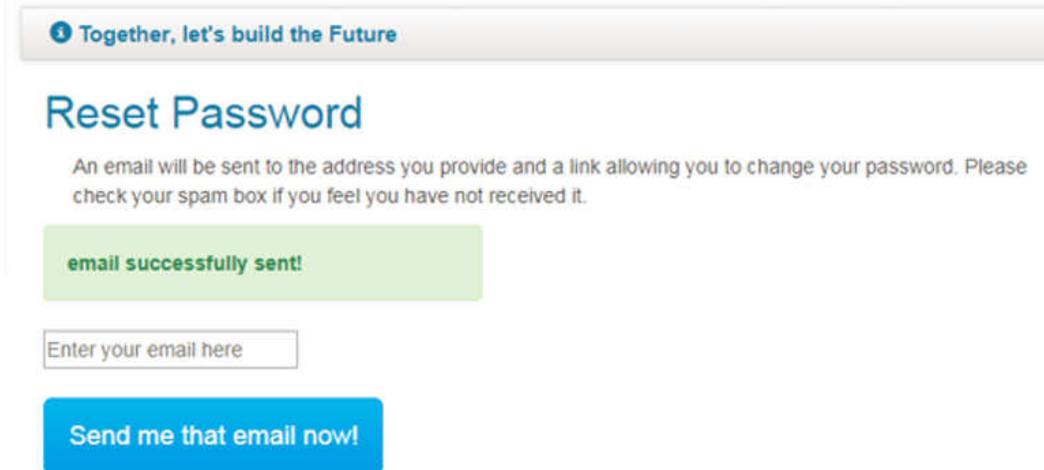
Forgot Your Password Screens

- Allows user to reset their password by entering their user email address



The screenshot shows a web interface with a header "Together, let's build the Future". Below it is the title "Reset Password" and a sub-header "An email will be sent to the address you provide and a link allowing you to change your password. Please check your spam box if you feel you have not received it." There is an input field labeled "Enter your email here". Below the input field is a reCAPTCHA widget with the text "I'm not a robot" and a reCAPTCHA logo. At the bottom is a blue button labeled "Send me that email now!".

- User enters email address, completes the reCAPTCHA requirement, and selects the "Send me that email now!" button
- The following screen displays with a success message



The screenshot shows the same web interface as the previous one, but with a green success message box that says "email successfully sent!". The input field and the "Send me that email now!" button are still visible below the message.

- Reset Password email should be received as below:

Hi [@username],

Someone recently requested a password change to your HMUS Quality Control account. If this was you, you can set a new password here using the following link within the next 48 hours to complete the process!

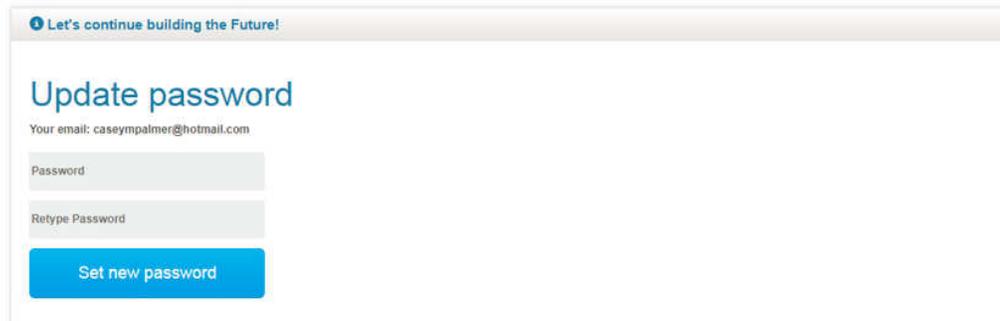
[Reset password](#)

If you do nothing, your password will NOT be reset! If you don't want to change your password or didn't request this, just ignore and delete this message.

To keep your account secure, please don't forward this email to anyone.

Thank you for participating in HORIBA US Quality Control Program.

- Clicking the "Reset password" link in the email redirects the user to the site to reset password
- User enters the password twice in the fields and selects "Set new password"



Let's continue building the Future!

Update password

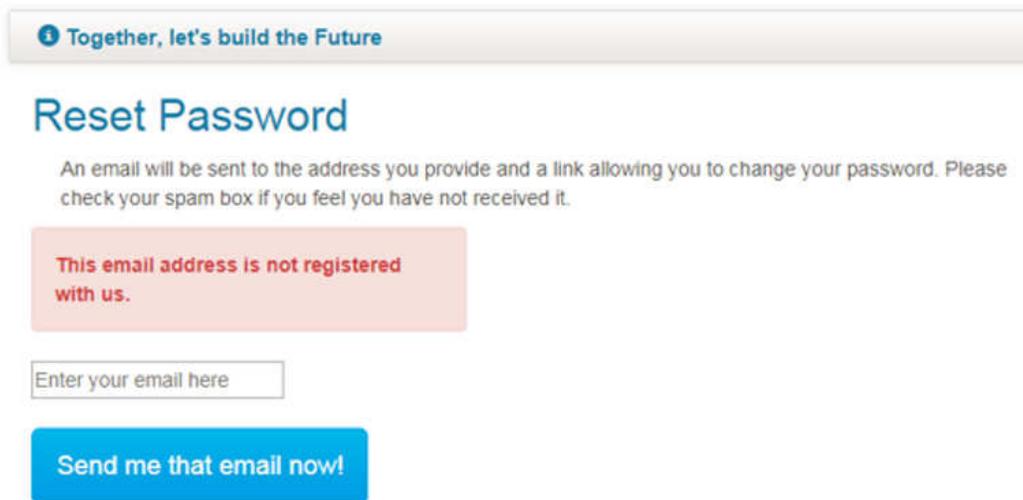
Your email: caseympalmer@hotmail.com

Password

Retype Password

[Set new password](#)

- If the user's email is not in the database, a message to the user will be displayed indicating they are not a registered user



Together, let's build the Future

Reset Password

An email will be sent to the address you provide and a link allowing you to change your password. Please check your spam box if you feel you have not received it.

This email address is not registered with us.

[Send me that email now!](#)

Enroll Screen

- The Initial Customer Account allows to self-enrollment for a QC Site account by filling out the required information on this screen
- The enrollment requires approval from a HORIBA Admin before the QC Site Account is active and the account owner is able to log in
- Additional Account users are setup in the Account once the Account is active. These users do not require HORIBA Admin approval
- The fields marked as required must have data before the enrollment can be completed
- Terms and conditions must be reviewed and accepted before the "Enroll me now" button is available (see section 1.1)

The screenshot shows the 'New Account Enrollment' form on the HORIBA Quality Control Program website. The form includes a navigation menu on the left with options for Home, Login, Enroll, and Contact Us. The main form area contains the following fields and sections:

- Account Name:** A single-line text input field.
- Account Contact:** A section containing several fields:
 - First Name:** Text input field.
 - Last Name:** Text input field.
 - Telephone:** Text input field.
 - Street Address 1:** Text input field.
 - Street Address 2:** Text input field.
 - City:** Text input field.
 - State:** A dropdown menu.
 - Zip:** Text input field.
 - Email:** Text input field.
 - Password:** Text input field.
 - Retype Password:** Text input field.
- Password Requirements:** A list of requirements: 'A lowercase letter', 'A capital (uppercase) letter', 'A number', and 'Minimum 8 characters'.
- Terms and Conditions:** A checkbox labeled 'You must reviewed the terms and conditions and accept in order to continue.'
- Anti-Bot:** A checkbox labeled 'I'm not a robot' with a CAPTCHA image.
- Enroll me now:** A blue button at the bottom of the form.

Example email sent to account user after enrollment:

Hi [@username],

Well done! Your enrollment request has been successfully submitted. You should receive an email when your account has been reviewed, approved and activated, which could take up to 24 hours. Please make sure to also check your spam folder for this email. If you do not receive an email within 24 hours, please contact our Technical Support Department at 1-888-903-5001 Option 3.

Thank you for participating in HORIBA US Quality Control Program.

Example email sent to account user after approval and activation:

Hi [@username],

Well done! Your enrollment has been successfully completed and activated. Please use the URL below to log in and complete the initial setup by creating a facility and instrument. Log In: <http://rt.qchoriba.com/login>

Please Contact HORIBA Medical Technical Support at 1-888-903-5001 Option 3, with any questions.

Contact Us Screen

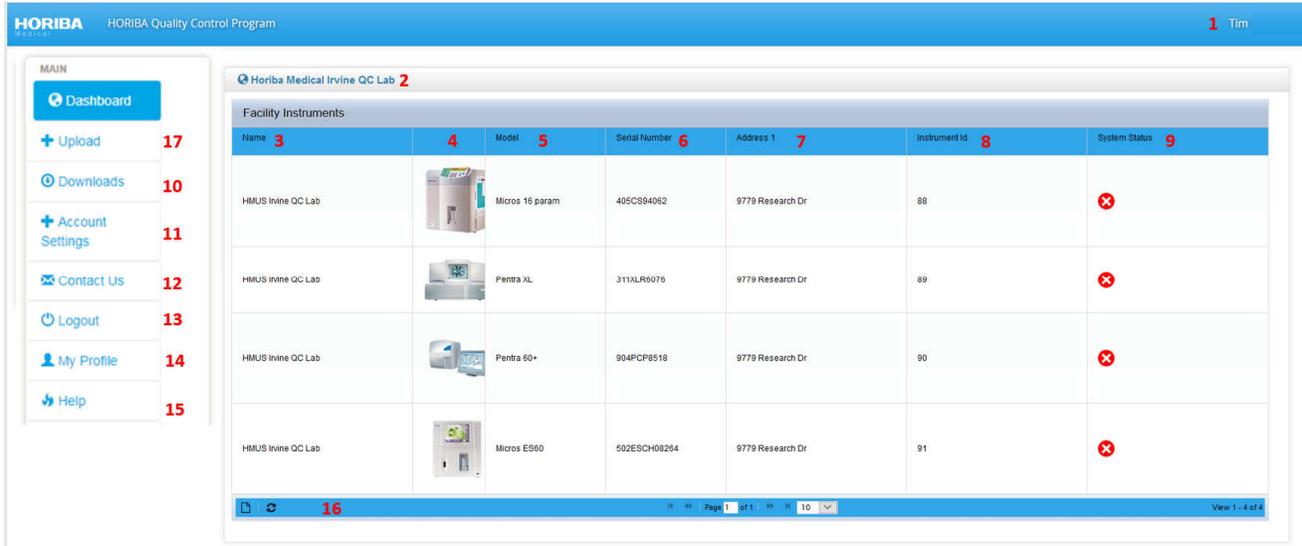
- Allows a user to submit a contact request from the site to HMUS

The screenshot shows the 'Contact Us' page on the HORIBA website. The header includes the HORIBA logo and the tagline 'HORIBA Interlaboratory Comparison for Quality Control'. A navigation menu on the left lists 'Home', 'Login', 'Enroll', and 'Contact Us'. The main content area features a 'Contact Us' form with the following fields: 'Account Name', 'From/Contact Name', 'Call back number', 'Email Address', and 'Instrument Serial Number'. A 'Message' field is also present. A reCAPTCHA 'I'm not a robot' checkbox is located at the bottom of the form. A 'Submit' button is at the bottom right of the form. On the right side of the page, there is a map showing the location of HORIBA Medical US at 9755 Research Drive, Irvine, California. Below the map, the contact information is listed: 'HORIBA Medical, 9755 Research Drive, Irvine, California CA 92618 USA, 949-453-0500'. There are also links for 'Hotline Email', 'Marketing info email', 'Sales info email', and 'Business hours'.

- User enters business entity name, first and last name of contact, telephone number, email address, instrument serial number (if known), and other message details into the Message field, completes the reCAPTCHA requirement, and selects the "Submit" button
- Horiba administrator will receive an email with the information and respond

Dashboard Screen

- Once a user is logged into the site, they will be presented with the “Dashboard” displaying the Facility Instruments that have been created
- Account Users will have all Facility Instruments displayed
- Facility Users will have Instruments displayed at the Facility where they have access
- Clicking on / selecting a Facility Instrument row will display the Quality Control information of that instrument



#	Item	Type	Description
1	User Name	Display	Logged in User Name
2	Account Name	Display	Account Name associated with User
3	Name	Display	Facility Names User has access
4	Image	Display	Instrument Model Image
5	Model	Display	Instrument Model Description
6	Serial Number	Display	Instrument Serial Number
7	Address 1	Display	Facility Address
8	Instrument ID	Display	Assigned number given to instrument by the Site
9	System Status	Display	Status icon indicating the quality control status of the instrument
10	Downloads	Navigation	Navigates to Downloads screen
11	+Account Settings	Menu	Expands the Accounts Settings Menu
12	Contact Us	Navigation	Navigates to Contact Us screen
13	Logout	Navigation	Navigates to Login screen (User is logged out of the Site)
14	My Profile	Navigation	Navigates to My Profile screen
15	Help	Navigation	Navigates to the Help screen
16	Table Footer Tool Bar	Function Buttons	View selected row, Reload table Grid, Records per Page selection
17	+Upload	Menu	Expands the Upload Menu

Quality Control Information

- Allows User to view and download Instrument Statistics for a date range by lot and level
- Allows User to view and download Peer Statistic for a date range by lot and level
- Allows User to view, ignore, and download Run Details for a date range by lot and level
- Allows User to generate a Levey Jennings Chart report for a date range by lot and level
- Allows User to generate a Performance Index report for a date range by lot and level
- Allows User to generate a QC Lot Details Report for a date range by lot and level

The screenshot shows a web application interface for 'ABC Lab / South Lab Instruments'. At the top, there is a 'Date Range' filter set to 'All'. Below this is a table with columns: Image, Model, Serial Number, and Status. The first row shows an image of a 'Micros 16 param' instrument with serial number '111CS99999' and a status icon of a red 'X'. Below the table, there are dropdown menus for 'QC Lot' (MX422), 'Level' (Low), and 'Exp' (2020-05-05). A section titled 'Instrument Statistics N=42' contains a table with 16 columns: Statistic, WBC, RBC, HGB, HCT, MCV, MCH, MCHC, RDW, PLT, MPV, LYM%, LYM#, MON%, MON#, GRA%, and GRA#. The table includes rows for Assay High, Assay Target, Assay Low, Mean, Mean Diff, SD, and CV. At the bottom of the statistics table, there are two function buttons: a download icon and a refresh icon.

#	Item	Type	Description
0	Date Range Or 	Function Button	Opens the Date range filter window where a user can select a specific date range to apply to the entire instrument QC screen Step 1: User selects the button and deselects All runs Step 2: User selects a start and end date Step 3: User selects Apply Step 4: User selects Apply and instrument QC screen is updated
1	Name	Display	Account/Facility Name
2	Instrument row	Display	Instrument Image, Description, Serial number, and Status
3	QC lot:	Dropdown	User selects QC lot from list (screen automatically refreshes)
4	Level:	Dropdown	User selects QC level from list (screen automatically refreshes)
5	Exp:	Display	Quality Control Lot Expiration Date
6	SID:	Display	QC Sample Identification values acceptable for data upload to the Site for the selected QC lot and level
7		Function Button	Generates the QC Lot Details tabular report for view and download
8		Function Button	Generates the Levey Jennings QC Chart report for view and download
9		Function Button	Generates the Performance Index Peer Comparison Chart report for view and download
10	Table Header	Display	Instrument Statistics table, N= number of data runs included
11	Table Data	Display	QC lot assay information and comparable instrument statistics
12	Table Footer Tool Bar	Function Buttons	Generate .csv file of table data for view and download Reload table Grid

13 Run Details Press F5 To Refresh This Page If You Make Changes Below

Run DateTime	Peer Ignored	My Ignore	WBC	WBC FL	RBC	RBC FL	HGB	HGB FL	HCT	HCT FL	MCV	MCV FL	MCH	MCH FL	MCHC	Comment	Web User
2020-05-02 08:29:11	<input checked="" type="checkbox"/>	<input type="checkbox"/>	2.10		2.35		8.11		16.8		69		25.4		36.6		
2020-04-30 15:04:27	<input type="checkbox"/>	<input type="checkbox"/>	2.00		2.35		6.2		16.8		69		25.4		36.6		
2020-04-29 18:33:19	<input type="checkbox"/>	<input checked="" type="checkbox"/>	2.00		2.35		6.2		16.8		69		25.4		36.6		
2020-04-29 18:24:43	<input type="checkbox"/>	<input checked="" type="checkbox"/>	2.00		2.40		6.3		16.6		67		25.2		36.8	Example	TH
2020-04-28 18:30:56	<input type="checkbox"/>	<input type="checkbox"/>	2.30		2.40		6.3		16.6		67		25.2		36.8		
2020-04-09 16:15:24	<input checked="" type="checkbox"/>	<input type="checkbox"/>	0.30		2.40		6.3		16.6		67		25.2		36.8		
2020-04-09 13:06:55	<input checked="" type="checkbox"/>	<input type="checkbox"/>	2.30		2.40		6.3		16.6		67		25.2		36.8		
2020-04-09 13:02:05	<input checked="" type="checkbox"/>	<input type="checkbox"/>	2.30		2.40		6.3		16.6		67		25.2		36.8		
2020-04-06 14:34:15	<input checked="" type="checkbox"/>	<input type="checkbox"/>	2.30		2.40		6.3		16.6		67		25.2		36.8	Flagged or >4SD	TH
2020-03-29 17:12:07	<input type="checkbox"/>	<input type="checkbox"/>	2.30		2.40		6.3		16.6		67		25.2		36.8		

16 < >

17 Page 1 of 3 10 View 1 - 10 of 22

#	Item	Type	Description
13	Table Header	Display	Run Details table (If runs are ignored or included, user must refresh screen in order for the statistics tables to update)
14	Search Bar	Tool Bar	Data is filtered by entering a value or selections from a dropdown
15	Run Data	Display	Date and time of run, values of each parameter, ↑ above or ↓ below the 2SD range indicators for each value, flags for each parameter, peer ignored indicator, my ignore selection, comments, and user ID
16	Scroll Bar	Tool Bar	Allows user to scroll the table left and right to view more parameter information columns
17	Table Footer Tool Bar	Function Buttons	<ul style="list-style-type: none"> Generate .csv file of table data for view and download Toggles viewing the inline search bar Reload table Grid Edit a selected row for the My Ignore function  <p>Rows per page selection, display, and page navigation</p>
18	Peer Ignored Indicator	Display	<p>QC values outside 4SD from the published assay target are automatically ignored for peer and instrument statistics</p> <p>Flagged QC is not acceptable even though value may be within the published assay 4SD range and is automatically ignored for peer and instrument statistics</p> <p>Flags are displayed in pink</p> <p>Refer to the Instrument User Manuals for a detailed description of all Instrument related flags</p>
19	My Ignore Selection	Display and Function Tool	<p>Displays the status of the run to be included in, or ignored from, the peer and instrument statistics by the user</p> <p>Selecting (highlighting in yellow) a row and then using the edit function button allows the user to change the status, enter in a comment, and enter a web user identifier</p> <p>Double clicking a row also allows edit of the record</p>  <p>User selects Submit for the information to save into the table</p> <p>The screen must be refreshed after a status change in order for the statistics' tables to update</p> <p>Peer ignored runs can be selected as my ignore, but no change in statistics will occur as they were already ignored</p>

20 124 unique instruments use this control level

21 Peer Statistic

Statistic	WBC	RBC	HGB	HCT	MCV	MCH	MCHC	RDW	PLT	MPV	LYM%	LYM#	MON%	MON#	GRA%	GRA#
Account Mean	1.983	2.270	5.810	16.055	70.762	25.614	36.236	14.026	80.357	8.783	60.971	1.164	10.595	0.181	28.433	0.638
Account SD	0.062	0.030	0.096	0.266	0.983	0.338	0.666	0.248	5.355	0.264	1.252	0.048	0.692	0.040	1.133	0.049
Instrument Account SDI	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000
Account Runs	42	42	42	42	42	42	42	42	42	42	42	42	42	42	42	42
Account CV	3.1%	1.3%	1.6%	1.7%	1.4%	1.3%	1.8%	1.8%	6.7%	3.0%	2.1%	4.2%	6.5%	22.0%	4.0%	7.7%
Facility Mean	1.983	2.270	5.810	16.055	70.762	25.614	36.236	14.026	80.357	8.783	60.971	1.164	10.595	0.181	28.433	0.638
Facility SD	0.062	0.030	0.096	0.266	0.983	0.338	0.666	0.248	5.355	0.264	1.252	0.048	0.692	0.040	1.133	0.049
Instrument Facility SDI	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000
Facility Runs	42	42	42	42	42	42	42	42	42	42	42	42	42	42	42	42
Facility CV	3.1%	1.3%	1.6%	1.7%	1.4%	1.3%	1.8%	1.8%	6.7%	3.0%	2.1%	4.2%	6.5%	22.0%	4.0%	7.7%
Peer Mean	2.035	2.348	6.116	16.657	70.951	26.074	36.766	13.733	77.866	8.155	62.244	1.216	10.496	0.175	27.387	0.646
Peer SD	0.095	0.063	0.160	0.505	1.123	0.570	0.909	0.447	8.069	0.446	1.521	0.071	0.897	0.044	1.380	0.063
Peer Runs	4189	4189	4189	4189	4189	4189	4189	4189	4189	4189	4189	4189	4189	4189	4189	4189
Peer CV	4.7%	2.7%	2.6%	3.0%	1.6%	2.2%	2.5%	3.3%	10.4%	5.5%	2.4%	5.8%	8.5%	24.9%	5.0%	9.8%
Instrument SDI	-0.542	-1.245	-1.913	-1.192	-0.169	-0.806	-0.583	0.656	0.309	1.410	-0.837	-0.727	0.110	0.131	0.758	-0.118
Instrument PI	0.669	0.498	0.629	0.546	0.878	0.604	0.743	0.543	0.643	0.550	0.840	0.714	0.764	0.880	0.790	0.785

25  

#	Item	Type	Description
20	# of unique instruments	Display	# of unique instruments that have posted data to the Site for the current lot and level selected from the dropdown lists Indicates the number of instruments in the All Peer Statistics
21	Table Header	Display	Peer Statistics table
22	Account Peer data Instrument Account SDI	Display	Peer Statistics of only the instruments under this account using this quality control lot and level Standard Deviation Index of the instrument as compared to this account's total instrument included runs
23	Facility Peer data Instrument Facility SDI	Display	Peer Statistics of only the instruments under this facility using this quality control lot and level Standard Deviation Index of the instrument as compared to this facility's total instrument included runs
24	All Peer data Instrument SDI Instrument PI	Display	Peer Statistics of all instruments on the Site using this quality control lot and level (see Item #10) Standard Deviation Index of the instrument as compared to the Site's total instrument included runs Performance Index of the instrument: Instrument CV/Peer CV
25	Table Footer Tool Bar	Function Buttons	 Generate .csv file of table data for view and download  Reload table Grid

Quality Control Calculations

- Quality control calculations are used to determine if the instrument is performing as expected as well as provide comparisons against other groups of instruments
 - Instrument Statistics
 - Only results for the selected instrument included in the date range and not ignored are used in these calculations

QC Lot: Level: Exp:2020-07-05 SID:MX423N.4232

Instrument Statistics N=37																
Statistic	WBC	RBC	HGB	HCT	MCV	MCH	MCHC	RDW	PLT	MPV	LYM%	LYM#	MON%	MON#	GRA%	GRA#
Assay High	8.70	4.84	14.3	40.2	85	31.4	39.3	16.0	304	9.7	39.0	3.10	11.0	0.90	65.0	5.30
Assay Target	7.90	4.66	13.7	37.7	81	29.4	36.3	13.0	264	7.7	34.0	2.70	7.0	0.60	59.0	4.70
Assay Low	7.10	4.48	13.1	35.2	77	27.4	33.3	10.0	224	5.7	29.0	2.30	3.0	0.30	53.0	4.10
1 Mean	8.097	4.790	13.911	38.462	80.189	29.065	36.184	13.397	281.216	7.878	32.095	2.549	8.041	0.595	59.865	4.954
2 Mean Diff	0.197	0.130	0.211	0.762	-0.811	-0.335	-0.116	0.397	17.216	0.178	-1.905	-0.151	1.041	-0.005	0.865	0.254
3 SD	0.157	0.075	0.151	0.631	0.397	0.347	0.444	0.189	8.696	0.120	0.503	0.077	0.324	0.033	0.543	0.107
4 CV	1.9%	1.6%	1.1%	1.6%	0.5%	1.2%	1.2%	1.4%	3.1%	1.5%	1.6%	3.0%	4.0%	5.5%	0.9%	2.2%

#	Item	Description
1	Mean	<p>Average value of all the included runs for each parameter</p> <p>Mean = $\frac{\text{Sum of included instrument parameter values}}{\text{Total number of included instrument runs}}$</p> $\bar{x} = \frac{\sum x}{N}$
2	Mean Diff. – Mean Difference	<p>Difference between the assay target (mean) and calculated mean for each parameter</p> <p>Mean Diff. = Calculated Mean – Assay Target</p>
3	SD – Standard Deviation	<p>A measure of the dispersion of a group of values around a mean for each parameter</p> <p>95% of all results in a normal data population fall within 2 SDs of the mean</p> <p>Therefore, + or - 2 SD is considered an acceptable laboratory standard</p> $SD = \sqrt{\frac{\sum(x - \bar{x})^2}{N - 1}}$
4	CV – Coefficient of Variation	<p>The Standard Deviation expressed as a percentage of the mean for each parameter for the selected instrument</p> <p>The smaller the CV, the more precise is the analytic method</p> $\%CV = \frac{SD}{\text{Mean}} \times 100$

- Peer Statistics
 - Peer- An instrument from a group of similar instrument types, using the same control product of the same lot and level
 - Peer Group- Group of similar instrument types, using the same control product of the same lot and level
 - Account Statistics: Comparison of the selected instrument against the same instrument types using the same control lot and level within the selected instrument's Account
 - In the event there is only one instrument of a given type in the Account then the Account Statistics will match that of the Instrument Statistics
 - Only results included in the date range and not ignored are used in these calculations

Peer Statistic																
Statistic	WBC	RBC	HGB	HCT	MCV	MCH	MCHC	RDW	PLT	MPV	LYM%	LYM#	MON%	MON#	GRA%	GRA#
1 Account Mean	8.092	4.664	13.774	37.497	80.357	29.553	36.756	13.493	278.531	7.910	33.458	2.653	7.516	0.556	59.026	4.883
2 Account SD	0.148	0.117	0.178	0.917	0.482	0.543	0.623	0.240	8.528	0.144	1.279	0.115	0.541	0.052	0.908	0.122
3 Instrument Account SDI	0.037	1.072	0.764	1.053	-0.349	-0.900	-0.918	-0.398	0.315	-0.221	-1.066	-0.907	0.969	0.741	0.924	0.586
4 Account Runs	98	98	98	98	98	98	98	98	98	98	98	98	98	98	98	98
5 Account CV	1.8%	2.5%	1.3%	2.4%	0.6%	1.8%	1.7%	1.8%	3.1%	1.8%	3.8%	4.3%	7.2%	9.3%	1.5%	2.5%

#	Item	Description
1	Account Mean	Average value of all the Account instruments' included runs for each parameter of the same instrument type, control lot, and control level
2	Account SD	Measurement of the dispersion around the Account Mean of all the Account instruments' included runs for each parameter of the same instrument type, control lot, and control level
3	Instrument Account SDI	Standard Deviation Index is a measure of Relative Accuracy to show how close a Mean is to the Group Mean The number of Account Standard Deviations by which an Instrument Mean differs from the Account Mean $\frac{(\text{Instrument Mean} - \text{Account Mean})}{\text{Account SD}}$ An SDI value between - 2 and + 2 defines acceptable performance The closer the absolute value is to 2 the greater the potential for an accuracy problem
4	Account runs	Number of included runs for each parameter for all the Account instruments of the same instrument type, control lot, and control level
5	Account CV	The Account Standard Deviation expressed as a percentage of the Account Mean for all the Account instruments' included runs for each parameter of the same instrument type, control lot, and control level

- Facility Statistics: Comparison of the selected instrument against the same instrument types using the same control lot and level within the selected instrument's Facility
- In the event there is only one instrument of a given type in the Account or Facility then the Facility Statistics will match that of the Instrument Statistics
- Only results included in the date range and not ignored are used in these calculations

6	Facility Mean	8.097	4.790	13.911	38.462	80.189	29.065	36.184	13.397	281.216	7.878	32.095	2.549	8.041	0.595	59.885	4.954
7	Facility SD	0.157	0.075	0.151	0.631	0.397	0.347	0.444	0.189	8.696	0.120	0.503	0.077	0.324	0.033	0.543	0.107
8	Instrument Facility SDI	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000
9	Facility Runs	37	37	37	37	37	37	37	37	37	37	37	37	37	37	37	37
10	Facility CV	1.9%	1.6%	1.1%	1.6%	0.5%	1.2%	1.2%	1.4%	3.1%	1.5%	1.6%	3.0%	4.0%	5.5%	0.9%	2.2%

#	Item	Description
6	Facility Mean	Average value of all the Facility instruments' included runs for each parameter of the same instrument type, control lot, and control level
7	Facility SD	Measurement of the dispersion around the Facility Mean of all the Facility instruments' included runs for each parameter of the same instrument type, control lot, and control level
8	Instrument Facility SDI	<p>The number of Facility Standard Deviations by which an Instrument Mean differs from the Facility Mean</p> $\frac{(\text{Instrument Mean} - \text{Facility Mean})}{\text{Facility SD}}$ <p>An SDI value between - 2 and + 2 defines acceptable performance The closer the absolute value is to 2 the greater the potential for an accuracy problem</p>
9	Facility runs	Number of included runs for each parameter for all the Facility instruments of the same instrument type, control lot, and control level
10	Facility CV	The Facility Standard Deviation expressed as a percentage of the Facility Mean for all the Facility instruments' included runs for each parameter of the same instrument type, control lot, and control level

- Peer Statistics: Comparison of the selected instrument against the same instrument types using the same control lot and level within the entire Site (All Peers)
- Only results included in the date range and not ignored are used in these calculations

11	Peer Mean	8.019	-4.665	13.640	37.575	80.586	29.264	36.338	13.511	268.533	7.613	33.897	2.667	7.455	0.547	58.730	4.808
12	Peer SD	0.268	0.106	0.267	0.893	0.852	0.481	0.624	0.430	13.970	0.317	1.014	0.126	0.468	0.053	0.940	0.182
13	Peer Runs	3123	3123	3123	3123	3123	3123	3123	3123	3123	3123	3123	3123	3123	3123	3123	3123
14	Peer CV	3.3%	2.3%	2.0%	2.4%	1.1%	1.6%	1.7%	3.2%	5.2%	4.2%	3.0%	4.7%	6.3%	9.7%	1.6%	3.8%
15	Instrument SDI	0.295	1.179	1.015	0.993	-0.466	-0.414	-0.248	-0.264	0.908	0.837	-1.777	-0.939	1.252	0.901	1.207	0.804
16	Instrument PI	0.582	0.690	0.553	0.690	0.468	0.727	0.714	0.444	0.594	0.367	0.524	0.638	0.642	0.568	0.566	0.570

#	Item	Description
11	Peer Mean	Average value of all the Site instruments' included runs for each parameter of the same instrument type, control lot, and control level (All Peers)
12	Peer SD	Measurement of the dispersion around the Peer Mean of all the Site instruments' included runs for each parameter of the same instrument type, control lot, and control level
13	Peer runs	Number of included runs for each parameter for all the Site instruments of the same instrument type, control lot, and control level
14	Peer CV	The Peer Standard Deviation expressed as a percentage of the Peer Mean for all the Site instruments' included runs for each parameter of the same instrument type, control lot, and control level
15	Instrument SDI- Standard Deviation Index	<p>The number of Peer Standard Deviations by which an Instrument Mean differs from the Peer Mean</p> $\frac{(\text{Instrument Mean} - \text{Peer Mean})}{\text{Peer SD}}$ <p>An SDI value between -0.5 and 0.5 is excellent, indicating an absence of bias compared to the Peer group An SDI value between 0.5 and 1.5 is satisfactory An SDI value between 1.5 and 2.0 should be investigated for inaccuracy An SDI value above 2.0 requires immediate attention</p>
16	Instrument PI- Precision Index	<p>Precision Index is a measure of Relative Precision calculated as the ratio of an Instrument's CV to the Peer CV</p> $\frac{\text{Instrument CV}}{\text{Peer CV}}$ <p>A PI value between 0 and +1.5 defines acceptable performance A PI value below 1.0 indicates a better performance A PI value close to 1.0 indicates a performance equivalent to the Peer group A PI value above 1.5 should be investigated for imprecision A PI value above 2.0 requires mandatory action</p>

- Investigate ignored and flagged data, as well as data beyond the +/- 2 SD assay range, to determine any cause for the unexpected results. See instrument User Manuals for further troubleshooting information

QC Lot Details Report

- Allows User to generate a tabular QC Lot Details report for review and download
- Includes the instrument statistics, run details, and peer statistics tables for all QC levels
- Only results included in the selected date range are displayed
- Title Page

HORIBA
Medical

1 QC Lot Details Report

2 ABC Lab

3 Facility Name: South Lab

4 CLIA: 54874211

5 Instrument: Micros 16 param

6 Serial Number: 111CS99999

7 Lot: MX422 MINOTROL

8 Report Type/QC Runs : Ad hoc / All

Page 1 of 7 08/17/2020 13:24

Reviewed by _____ Date _____

#	Description
1	Name of the Report
2	Account Name of selected Instrument
3	Facility Name of selected Instrument
4	Facility CLIA Number of selected Instrument
5	Selected Instrument Type
6	Serial Number of selected Instrument
7	Control Lot Number and description
8	Report type (Ad hoc or Site generated) and included QC runs (All or date range)

- Report and Legend

1 Low Level

Low Level Instrument Statistics N=3

Statistic	WBC	RBC	HGB	HCT	MCV	MCH	MCHC	RDW	PLT	MPV	LYMP%	LYMP#	MON%	MON#	GRA%	GRA#
Assay High	2.40	2.49	6.5	18.4	74	28.1	40.2	16.5	98	10.0	72.0	1.70	16.5	0.40	32.5	0.90
Assay Target	2.00	2.34	6.1	18.4	70	26.1	37.2	13.5	78	8.0	84.0	1.30	10.5	0.20	25.5	0.50
Assay Low	1.60	2.19	5.7	14.4	66	24.1	34.2	10.5	56	6.0	66.0	0.90	4.5	0.00	18.5	0.10
Mean	2.200	2.383	6.267	18.667	67.667	25.267	36.733	12.467	81.667	8.733	63.567	1.133	10.667	0.267	26.433	0.433
Mean Diff	0.200	0.043	0.167	0.267	-2.333	-0.833	-0.467	-1.033	5.667	0.733	-0.433	-0.167	0.167	0.007	0.933	-0.067
SD	0.173	0.029	0.058	0.115	1.155	0.115	0.115	0.115	1.155	0.115	0.115	0.115	1.155	0.115	0.115	0.115
CV	7.9%	1.2%	0.9%	0.7%	1.7%	0.5%	0.3%	0.9%	1.4%	1.3%	0.2%	10.2%	10.8%	43.3%	0.4%	26.6%

Low Level Run Details

Run Date/Time	PI	MI	WBC	RBC	HGB	HCT	MCV	MCH	MCHC	RDW	PLT	MPV	LYMP%	LYMP#	MON%	MON#	GRA%	GRA#	Comment	Web User Name
2020-06-02 08:29:11	X		2.10	2.35	8.1 ↑	16.8	69	25.4	36.6	12.6	83	8.6	63.7	1.00	12.0	0.40	26.3	0.30		
2020-04-30 15:04:27			2.00	2.35	6.2	16.8	69	25.4	36.6	12.6	83	8.6	63.7	1.00	12.0	0.40	26.3	0.30		
2020-04-29 18:33:19	X		2.00	2.35	6.2	16.8	69	25.4	36.6	12.6	83	8.6	63.7	1.00	12.0	0.40	26.3	0.30		
2020-04-29 18:24:43	X		2.00	2.40	6.3	16.6	67	25.2	36.8	12.4	81	8.8	63.5	1.20	10.0	0.20	26.5	0.50		
2020-04-28 18:30:56			2.30	2.40	6.3	16.6	67	25.2	36.8	12.4	81	8.8	63.5	1.20	10.0	0.20	26.5	0.50		
2020-04-09 16:15:24	X		0.30 ↓	2.40	6.3	16.6	67	25.2	36.8	12.4	81	8.8	63.5	1.20	10.0	0.20	26.5	0.50		
2020-04-09 13:06:55	X		2.30	2.40	6.3	16.6	67	25.2	36.8	12.4	81	8.8	63.5	1.20	10.0	0.20	26.5	0.50		
2020-04-09 13:02:05	X		2.30 *	2.40 *	6.3 *	16.6 *	67 *	25.2 *	36.8 *	12.4 *	81 *	8.8 *	63.5 *	1.20 *	10.0 *	0.20 *	26.5 *	0.50 *		
2020-04-06 14:34:15	X		2.30 *	2.40	6.3	16.6	67	25.2	36.8	12.4	81	8.8	63.5	1.20	10.0	0.20	26.5	0.50		
2020-03-29 17:12:07			2.30	2.40	6.3	16.6	67	25.2	36.8	12.4	81	8.8	63.5	1.20	10.0	0.20	26.5	0.50		

Low Level Peer Statistics : 2 unique instruments use this control level

Statistic	WBC	RBC	HGB	HCT	MCV	MCH	MCHC	RDW	PLT	MPV	LYMP%	LYMP#	MON%	MON#	GRA%	GRA#
Account Mean	2.200	2.383	6.267	18.667	67.667	25.267	36.733	12.467	81.667	8.733	63.567	1.133	10.667	0.267	26.433	0.433
Account SD	0.173	0.029	0.058	0.115	1.155	0.115	0.115	0.115	1.155	0.115	0.115	0.115	1.155	0.115	0.115	0.115
Instrument SDI	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000
Account Runs	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3
Account CV	7.9%	1.2%	0.9%	0.7%	1.7%	0.5%	0.3%	0.9%	1.4%	1.3%	0.2%	10.2%	10.8%	43.3%	0.4%	26.6%
Facility Mean	2.200	2.383	6.267	18.667	67.667	25.267	36.733	12.467	81.667	8.733	63.567	1.133	10.667	0.267	26.433	0.433
Facility SD	0.173	0.029	0.058	0.115	1.155	0.115	0.115	0.115	1.155	0.115	0.115	0.115	1.155	0.115	0.115	0.115
Facility SDI	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000
Facility Runs	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3
Facility CV	7.9%	1.2%	0.9%	0.7%	1.7%	0.5%	0.3%	0.9%	1.4%	1.3%	0.2%	10.2%	10.8%	43.3%	0.4%	26.6%
Peer Mean	2.200	2.383	6.267	18.667	67.667	25.267	36.733	12.467	81.667	8.733	63.567	1.133	10.667	0.267	26.433	0.433
Peer SD	0.173	0.029	0.058	0.115	1.155	0.115	0.115	0.115	1.155	0.115	0.115	0.115	1.155	0.115	0.115	0.115
Peer Runs	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3
Peer CV	7.9%	1.2%	0.9%	0.7%	1.7%	0.5%	0.3%	0.9%	1.4%	1.3%	0.2%	10.2%	10.8%	43.3%	0.4%	26.6%
Instrument SDI	0.173	0.029	0.058	0.115	1.155	0.115	0.115	0.115	1.155	0.115	0.115	0.115	1.155	0.115	0.115	0.115
Instrument PI	1.000	1.000	1.000	1.000	1.000	1.000	1.000	1.000	1.000	1.000	1.000	1.000	1.000	1.000	1.000	1.000

5

Legend

PI = Peer Ignore
 MI = My Ignore
 ↑ = Result value is greater than Assay High
 ↓ = Result value is less than Assay Low

Reviewed by _____ Date _____

Results with warning flags are displayed in pink

#	Item	Description
1	Header	QC Level (Low, Normal, High)
2	Instrument Statistics Table	N= number of data runs included QC lot assay information and comparable instrument statistics
3	Run Details Table	Date and time of run, peer ignored (PI) indicator (X=ignored), my ignore (MI) indicator (X=ignored), values of each parameter, ↑ above or ↓ below the 2SD range indicators for each value, flags for each value, comments, and user ID
4	Peer Statistics Table	Table header: # of unique instruments that have posted data to the Site for the lot and level selected from the dropdown lists Accounts Statistics: include all instruments under this account using this quality control lot and level Facility Statistics: include all instruments under this facility using this quality control lot and level Peer Statistics: include all instruments on the Site using this quality control lot and level Standard Deviation Index of the instrument: The number of Peer Standard Deviations by which an Instrument Mean differs from the Peer Mean Performance Index of the instrument: Instrument CV/Peer CV
5	Legend	Explanation of report items that differ slightly compared to the Site display

Levey Jennings Chart Report



- Allows User to generate a Levey Jennings QC Chart report for review and download
- Each parameter for each level of QC displays a chart
- Only results included in the date range and not ignored are displayed
- Title Page

HORIBA
Medical

1 Levey Jennings

2 ABC Lab

3 Facility Name: South Lab

4 CLIA:54874211

5 Instrument: Micros 16 param

6 Serial Number:111CS99999

7 Lot: MX225 Minotrol 16

8 Report Type/QC Runs : Ad hoc / All QC runs for lot

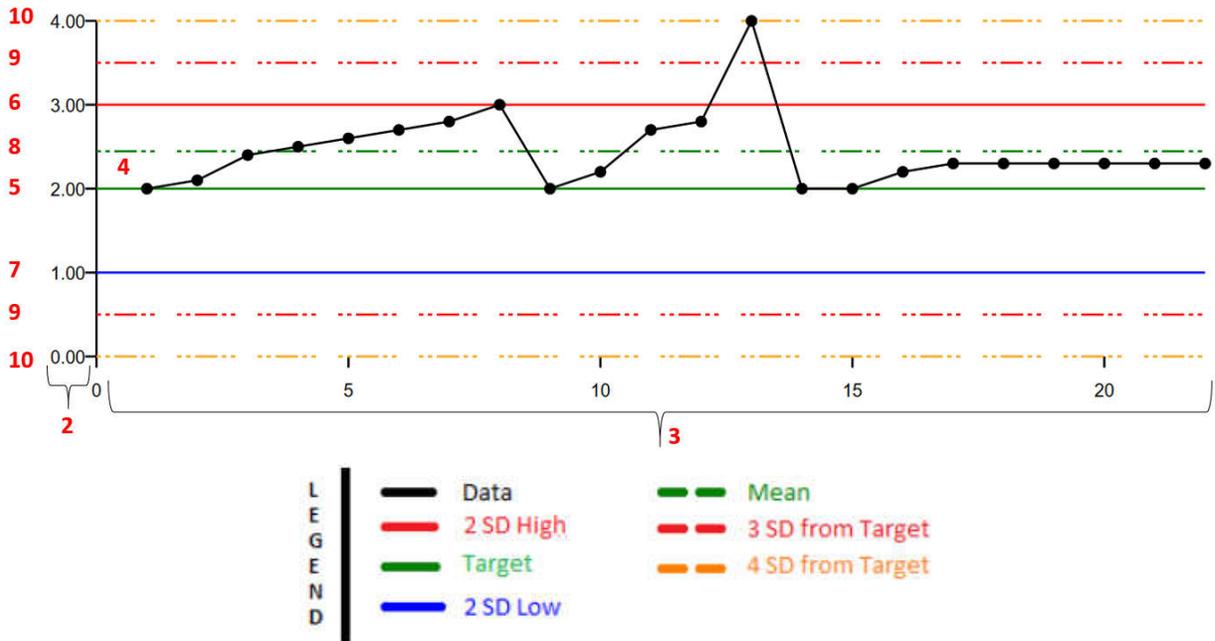
Page 1 of 17 06/15/2020 21:11

#	Description
1	Name of the Report
2	Account Name of selected Instrument
3	Facility Name of selected Instrument
4	Facility CLIA Number of selected Instrument
5	Selected Instrument Type
6	Serial Number of selected Instrument
7	Control Lot Number and description
8	Report type (Ad hoc or Site generated) and included QC runs (All or date range)

- Chart and Legend

Individual QC Tests

1 WBC level Low



#	Item	Description
1	Header	Parameter name and QC level
2	Y Axis	Numerical values displayed are based on published assay target and range
3	X Axis	Number of included data points, displayed chronologically left to right
4	Data	Included QC data points are plotted horizontally, chronologically by date and time from left to right and vertically by numerical value (Prior to June 27, 2020 data plotted right to left) The points are black and joined by a black line
5	Target	A peer group specific value published on the target sheet of the control product Displayed as a solid green line
6	2 SD High	2 standard deviations above the target Displayed as a red line
7	2 SD Low	2 standard deviations below the target Displayed as a blue line
8	Mean	Average value of all the included runs for each parameter Displayed as a dashed green line
9	3 SD from Target	+/- 3 standard deviations from the target Displayed as dashed red lines
10	4 SD From Target	+/- 4 standard deviations from the target Displayed as dashed orange lines QC values outside 4SD from the published assay target are automatically excluded from peer and instrument statistics

- Visually check the instrument's precision by comparing how far the plotted daily results vary from the mean

Performance Index Report



- Allows User to generate a Performance Index report for review and download
- This report enables user to quickly compare individual instrument results to the All Peer Group using the same control product, lot, and level on similar instrument types
- Each level of the control product is compared for each parameter
- Tile page

HORIBA
MEDICAL

1 Performance Index

2 ABC Lab

3 Facility Name: South Lab

4 CLIA:54874211

5 Instrument: Micros 16 param

6 Serial Number:111CS99999

7 Lot: MX225 Minotrol 16

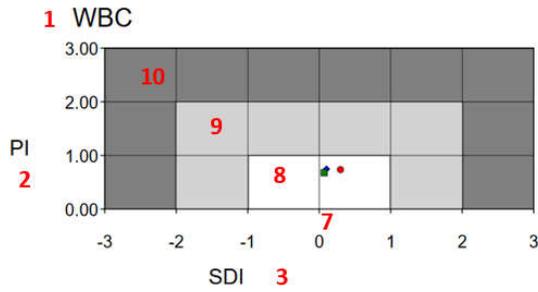
8 Report Type/QC Runs : Ad hoc / All QC runs for lot

Page 1 of 7 06/17/2020 16:55

#	Description
1	Name of the Report
2	Account Name of selected Instrument
3	Facility Name of selected Instrument
4	Facility CLIA Number of selected Instrument
5	Selected Instrument Type
6	Serial Number of selected Instrument
7	Control Lot Number and description
8	Report type (Ad hoc or Site generated) and included QC runs (All or date range)

- Chart and Legend

Individual QC Tests



4

WBC/ 10 ³ mm ³		Low	Normal	High
Instrument Runs:		36	36	34
Total Peer Runs:		134	132	131
Mean	Assay Target	2.500	7.500	17.600
	Instrument	2.474	7.639	17.673
	Peer	2.466	7.628	17.590
SD	Instrument	0.061	0.105	0.207
	Peer	0.081	0.155	0.280
2SD	Instrument	0.122	0.210	0.413
	Peer	0.162	0.310	0.559
SDI	Instrument	0.102	0.069	0.297
CV	Instrument	2.5%	1.4%	1.2%
	Peer	3.3%	2.0%	1.6%
PI	Instrument	0.748	0.677	0.736

5

6

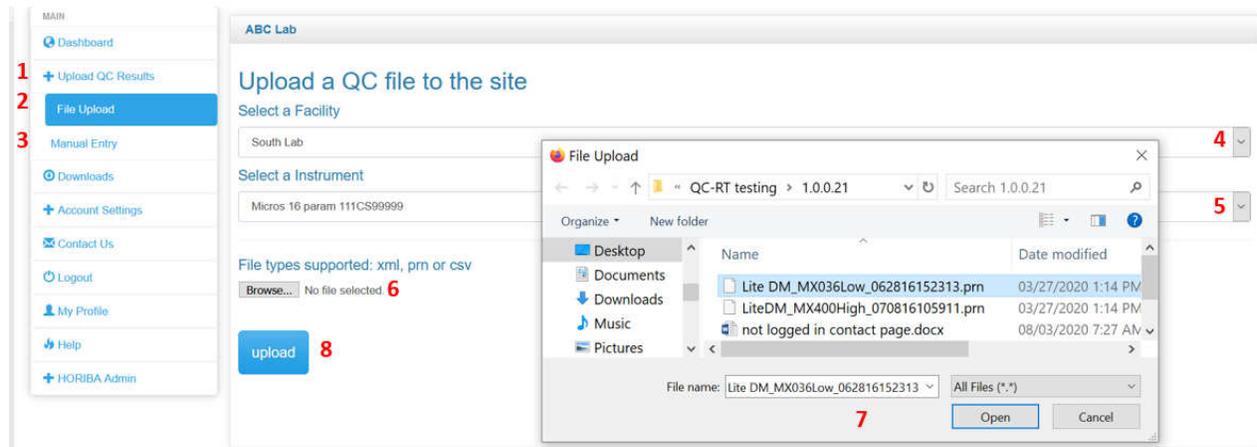
The information provided here comes from an automatic treatment of the entities given by users; HORIBA Medical has no control on the entries. Therefore, this report shall be used cautiously as it is given "as-is" without any express or implied warranty.

L E G E N D
 PI = Precision Index
 SDI = Accuracy Index
 L Low
 N Normal
 H High
 Ideal Zone
 Acceptable Zone
 Unacceptable Zone

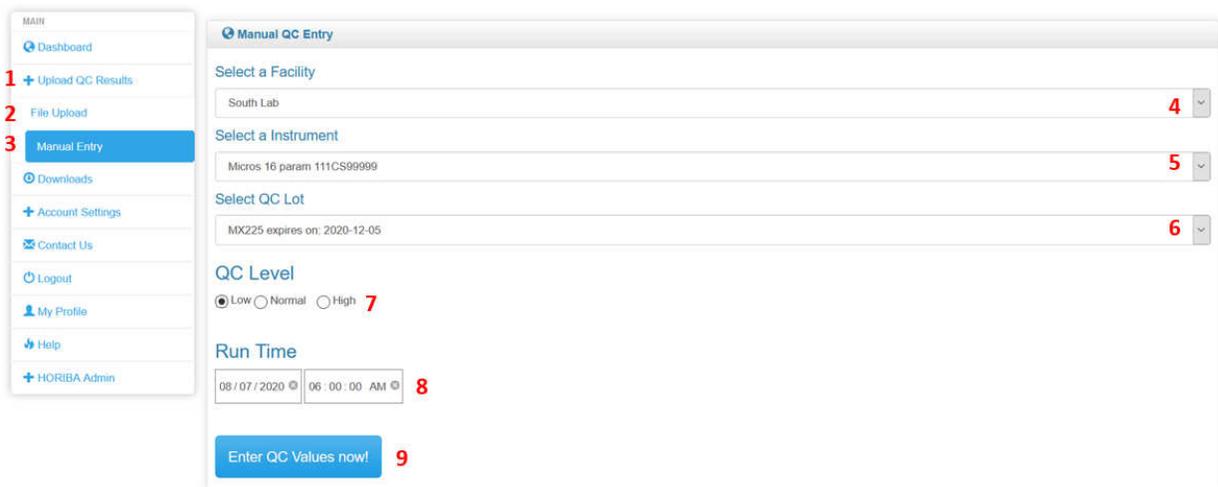
Reviewed by _____ Date _____

#	Item	Description
1	Header	Parameter name
2	Y Axis	Plotted Precision Index (see item 6 for numerical values)
3	X Axis	Plotted Accuracy Index (see item 5 for numerical values)
4	Data Table	Table of data for reference Drawn from the selected instrument and peer statistics for the selected QC lot
5	Instrument SDI-Standard Deviation Index	The number of Peer Standard Deviations by which an Instrument Mean differs from the Peer Mean
6	Instrument PI-Precision Index	Precision Index is a measure of Relative Precision calculated as the ratio of an Instrument's CV to the Peer CV
7	0	The Ideal Position (SDI = PI = 0)
8	Ideal Zone	An SDI value between -0.5 and 0.5 is excellent, indicating an absence of bias compared to the Peer group An SDI value between +/-0.5 and +/-1.5 is satisfactory A PI value between 0 and 1.5 defines acceptable performance A PI value below 1.0 indicates a better performance A PI value close to 1.0 indicates a performance equivalent to the Peer group
9	Acceptable Zone	An SDI value between +/-0.5 and +/-1.5 is satisfactory An SDI value between +/-1.5 and +/-2.0 should be investigated for inaccuracy A PI value between 0 and 1.5 defines acceptable performance A PI value between 1.5 and 2.0 should be investigated for imprecision
10	Unacceptable Zone	An SDI value above +/-2.0 requires immediate attention A PI value above 2.0 requires mandatory action

+Upload QC Results Menu and Screens



#	Item	Description
1	+Upload QC Results	Expands and contracts the menu
2	File Upload	Allows for import of a file containing quality control data in a specified format to be uploaded to a specific instrument's quality control screen
3	Manual Entry	Allows for data entry of quality control data one run at a time
2-4	Select a Facility	User chooses the facility where the pertinent instrument is located
2-5	Select a Instrument	User chooses the pertinent instrument
2-6	Browse for file	User selects the button to display the File Upload selection window
2-7	File Upload window	User navigates and chooses the pertinent file to upload
2-8	Upload button	User selects the button to upload the file
		The site will display a confirmation message when completed



#	Item	Description
1	+Upload QC Results	Expands and contracts the menu
2	File Upload	Allows for import of a file containing quality control data in a specified format to be uploaded to a specific instrument's quality control screen
3	Manual Entry	Allows for data entry of quality control data one run at a time
3-4	Select a Facility	User chooses the facility where the pertinent instrument is located
3-5	Select a Instrument	User chooses the pertinent instrument for the QC data run
3-6	Select QC Lot	User chooses the pertinent QC lot for the QC data run
3-7	QC Level	User chooses the pertinent QC level for the QC data run
3-8	Run Time	User enters the date and time associated with the QC data run
3-9	Enter QC Values now!	User selects button to display the Detail Manual QC Entry screen

Save and Finalize changes! **14**

Detail Manual QC Entry

- Instrument: Micros 16 param 405CS94062
- 10** Lot: MX425 Level:low
- Run Date/Time: 2020-09-23 at 07:28:00

Instructions:

- Click on the "Test" row to enter in values
- Enter values into the "Result" and "Flag" fields for the selected row
- 11** Press the Enter key to save the values into the temporary grid
- Continue entering values for each row, pressing the Enter key to save each time
- After all values have been entered, click the "Save and Finalize changes!" button located at the top of the window to permanently save to the database. (To abort all your entries, simply navigate to another page on the site prior to clicking "Save and Finalize changes!". Your entries will not be saved.)
- The screen will refresh to start the manual entry process over with a confirmation message displayed at the bottom "Successfully saved manual result for *date at time*"

QC Result Details		
Test	Result	Flag
WBC 12	<input type="text"/>	<input type="text"/>
RBC	<input type="text"/>	<input type="text"/>
HGB	<input type="text"/>	<input type="text"/>

13

#	Item	Description
3-10	Manual Entry Information	Displays information user selected from previous screen
3-11	Instructions	Displays instructions for user for data input
3-12	Test result row	Selecting (highlighting in yellow) a row allows the user to input the result value and any flags for the test. User must press the Enter key to save the values into the temporary grid
3-13	Test result rows	User continues to select test rows and input results until all data is saved into the table for the individual run
3-14	Save and Finalize changes!	User selects the button to upload the data run The site will display a confirmation message when completed

Downloads Screen

- Stores the peer reports generated monthly by the system and allows user to view, download and print these reports
- Stores quality control assay files that users can download and upload on their instruments (**not implemented**)
- Stores quality control assay sheets that users can download (**not implemented**)

The screenshot shows the HORIBA Quality Control Program interface. The top navigation bar includes the HORIBA logo, the program name, and a user name 'Casey'. A sidebar on the left provides navigation options: Dashboard, Upload, Downloads (highlighted), Account Settings, Contact Us, Logout, My Profile, and Help. The main content area is titled 'INSTITUTE' and is divided into two sections:

Reports 1

Facility	SN / Instrument type	QC Lot / QC Name	Created	Statistical Report	Levey Jennings
INSTITUTE	010CS89592...Micros 16 param	MX408...Minotrol MX408	2018-03-15 19:35_28_62__pl_697b1b5 35_28_62__l_7074079c		
INSTITUTE	010CS89592...Micros 16 param	MX409...Minotrol MX409	2018-03-15 19:35_28_62__pl_994abaf4 35_28_62__l_120e582d		
INSTITUTE	010CS89592...Micros 16 param	MX410...	2018-03-15 19:35_28_62__pl_2233c43 35_28_62__l_e8b490e7		

System: Assay And Target Values 2

Status	Instrument	QC Lot	Last Updated	Target Values	Assay Sheet
InActive	Micros 8 Param	55	2017-11-12 18:13:58	test.csv 3	test.pdf 4
Active	Pentra 400	REPRO	2017-11-12 18:14:03	test2.csv	test2.pdf

#	Item	Description
1	Reports	Monthly Site generated peer reports
2	System: Assay and Target Values	Quality control target files that can be downloaded and then unloaded into instrument software PDF versions of the quality control assay sheet
3	Link to Target File	Starts download
4	Link to PDF File	Starts download

+Account Settings Menu and Screens

- Select the +Account Settings button to expand or contract the menu
- Screens can only be accessed by a User with Account User authority

Facility/Instruments Screen

- Account Users can create one or more Facilities within the account
- One or more Instruments can then be created and assigned to a Facility
- Every Account must have at least 1 Facility, even if it is the same name as the account

The screenshot shows the 'Horiba Medical Irvine QC Lab 6' account settings page. The sidebar on the left contains a navigation menu with the following items:

- 1 +Account Settings
- 2 Facility/Instruments
- 3 Users
- 4 Notifications
- 5 Facility Westgard Settings
- Contact Us
- Logout
- My Profile
- Help
- HORIBA Admin

The main content area displays three tables:

- Account Information (7):** A table with columns: Name, Number, City, State, Status, Show Instrument Status, Expires, Last Updated. The row shows: Horiba Medical Irvine QC Lab, H5DE5872C, Irvine, CA, Active, , 2029-01-01, 2019-12-03 08:14:41.
- Facilities (8):** A table with columns: Name, CLIA, Medical Director, Address 1, City, Phone, Status, Contact First Name, Contact Last Name, Contact Phone, Contact Email. The row shows: HMUS Irvine QC Lab, 123456789, Francisco Chavama, 9779 Research Dr, Irvine, 9492788153, Active, Francisco, Chavama, 9492788153, francisco.chavama@.
- Instruments (9):** A table with columns: Model, Serial Number, Installed, Status, Mac Addr, GUID, Send Ack, Data Form, Internet IP, Netw. The rows show:
 - Micros 16 param, 405CS94062, 2019-12-0, Active, , , , , ABX, ,
 - Pentra 60+, 904PCP8518, 2019-12-0, Active, , , , , ASTM, ,
 - Pentra XL, 311XLR6076, 2019-12-0, Active, , , , , ABX, ,
 - Micros ES60, 502ESCH08264, 2019-12-0, Active, , , , , ABX, ,

#	Item	Type	Description
1	+Account Settings	Navigation	Expands and contracts the menu
2	Facility/Instruments	Navigation	Navigates to Facility/Instruments settings screen
3	Users	Navigation	Navigates to User settings screen
4	Notifications	Navigation	Navigates to Notifications settings screen
5	Facility Westgard Settings	Navigation	Navigates to Westgard settings screen
6	Account Name	Display	Account Name associated with logged in User
7	Account Information	Table	Account specific information
8	Facilities	Table	List of Facilities associated with the Account
9	Instruments	Table	List of Instruments associated with the selected (highlighted) Facility

#	Item	Description																				
7	Account Information	<p>Main account information</p> <table border="1"> <thead> <tr> <th>Item</th> <th>Description</th> </tr> </thead> <tbody> <tr> <td>Name</td> <td>Account Name</td> </tr> <tr> <td>Number</td> <td>Account Number – Unique to the Account</td> </tr> <tr> <td>City</td> <td>Account City</td> </tr> <tr> <td>State</td> <td>Account State</td> </tr> <tr> <td>Status</td> <td>Account Status – Must be active for users to access account</td> </tr> <tr> <td>Show Instrument Status</td> <td>Setting to show instrument status on Dashboard  or </td> </tr> <tr> <td>Expires</td> <td>Account Expiration</td> </tr> <tr> <td>Last Updated</td> <td>Last Updated Date and time</td> </tr> <tr> <td>Function Buttons</td> <td>  Reload table Grid  Edit a selected row </td> </tr> </tbody> </table> <p>Rows per page selection, display, and page navigation</p>	Item	Description	Name	Account Name	Number	Account Number – Unique to the Account	City	Account City	State	Account State	Status	Account Status – Must be active for users to access account	Show Instrument Status	Setting to show instrument status on Dashboard  or 	Expires	Account Expiration	Last Updated	Last Updated Date and time	Function Buttons	 Reload table Grid  Edit a selected row
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Users Screen

- Account Users can create other users within the Account
- Users can be created as Account Users or Facility Users
- Account Users can see all Facilities and Instruments within the Account and do not require Facility Access
- Facility Users can only see Facilities and Instruments within the Account to which they have been given Facility Access to by an Account User

#	Item	Description																		
1	Users	<p>Defined users for the Account</p> <table border="1"> <thead> <tr> <th>Item</th> <th>Description</th> </tr> </thead> <tbody> <tr> <td>Last Name</td> <td>User Last Name</td> </tr> <tr> <td>First Name</td> <td>User First Name</td> </tr> <tr> <td>Title</td> <td>User Title</td> </tr> <tr> <td>Email</td> <td>User Email</td> </tr> <tr> <td>Phone</td> <td>User Phone</td> </tr> <tr> <td>Status</td> <td>User Status (Active / Inactive)</td> </tr> <tr> <td>Authority</td> <td>Authority Level (Account User / Facility User) If Facility User, then must have Facility Access defined (#2)</td> </tr> <tr> <td>Function Buttons</td> <td> <ul style="list-style-type: none"> Add a new User's information to a new row Edit a selected (highlighted) User's information Delete a selected (highlighted) User's information Reload table Grid <p>Page 3 of 5 10 View 21 - 30 of 44</p> <p>Rows per page selection, display, and page navigation</p> </td> </tr> </tbody> </table>	Item	Description	Last Name	User Last Name	First Name	User First Name	Title	User Title	Email	User Email	Phone	User Phone	Status	User Status (Active / Inactive)	Authority	Authority Level (Account User / Facility User) If Facility User, then must have Facility Access defined (#2)	Function Buttons	<ul style="list-style-type: none"> Add a new User's information to a new row Edit a selected (highlighted) User's information Delete a selected (highlighted) User's information Reload table Grid <p>Page 3 of 5 10 View 21 - 30 of 44</p> <p>Rows per page selection, display, and page navigation</p>
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Notifications Screen

- **Not Implemented**
- Allows Account Users to define specific situations in which notifications should be generated and to which Users will receive the notifications

Facility Westgard Settings Screen

- **Not Implemented**

Contact Us Screen

- Allows a user to submit a contact request from the site to HMUS

HORIBA HORIBA Interlaboratory Comparison for Quality Control

MAIN

- Dashboard
- Upload QC Results
- Downloads
- Account Settings
- Contact Us**
- Logout
- My Profile
- Help
- HORIBA Admin

Together, let's build the Future

Please complete the required information.

Contact Us

* required data

South Lab

Account Name ABC Lab

From/Contact Name John Smith

The Call Back Number field is required.

Call back number 849-555-1212

Email Address john.smith@southlab.com

Instrument Serial Number

Message

I would like information on HORIBA's new chemistry system.

I'm not a robot

Submit

HORIBA Medical US
9755 Research Drive
Irvine, California CA 92618 USA
949-453-0500

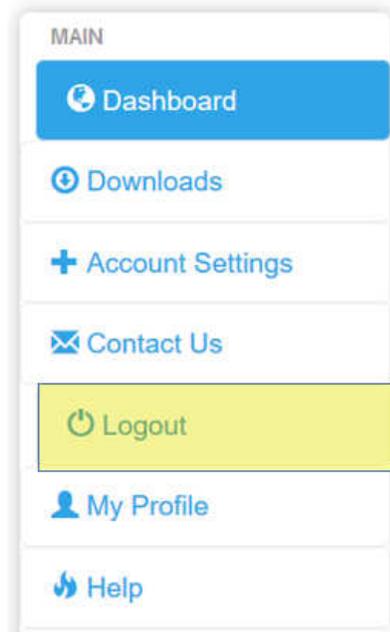
Hotline Email
Marketing info email
Sales info email

Business hours:

- User selects Facility from the dropdown list
- User enters first and last name in the From/Contact Name field, enters call back number and email address, instrument serial number (if pertinent), and other message details into the Message field, completes the reCAPTCHA requirement, and selects the "Submit" button
- Horiba administrator will receive an email with the information and respond

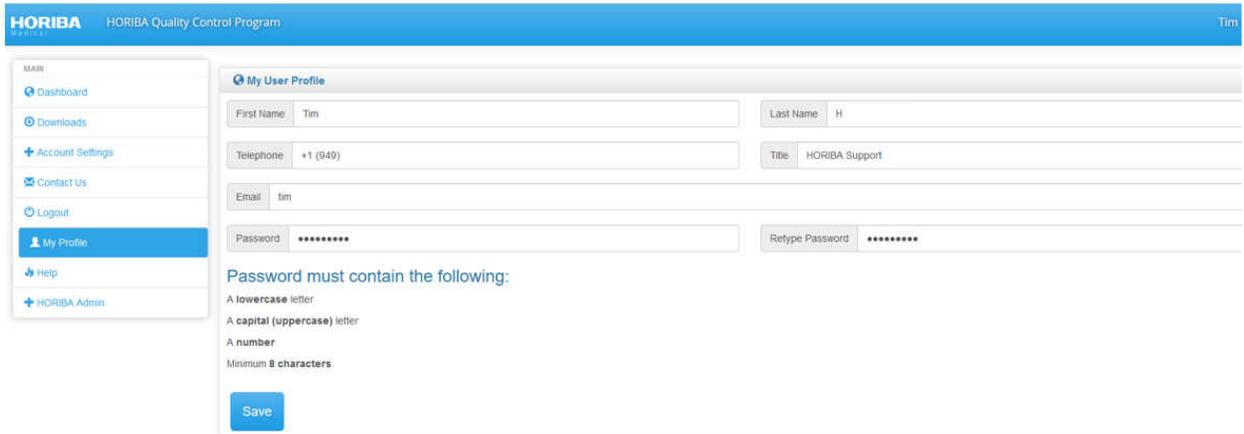
Logout

- Navigates to Login screen (User is logged out of the Site)



My Profile Screen

- Allows the user to edit their existing user profile



HORIBA HORIBA Quality Control Program Tim

My User Profile

First Name	Tim	Last Name	H
Telephone	+1 (949)	Title	HORIBA Support
Email	tim		
Password	*****	Retype Password	*****

Password must contain the following:

- A lowercase letter
- A capital (uppercase) letter
- A number
- Minimum 8 characters

Help Screen

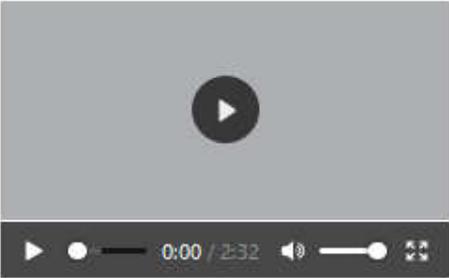
- Instructional Videos and User manual



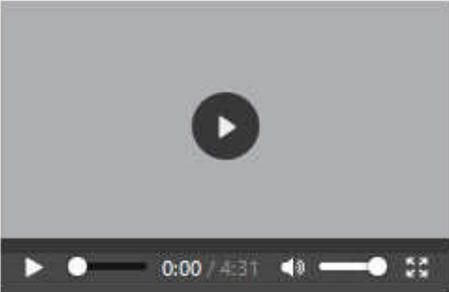


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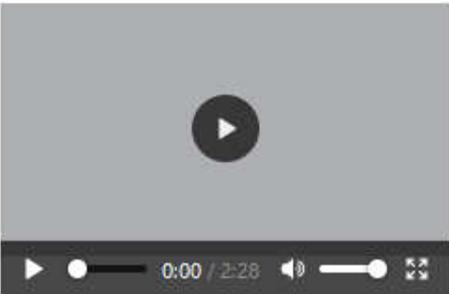
 **Enrollment**



 **Adding Users**



 **Facility and Instrument Setup**



[Click the full screen icon within the video image to enlarge.](#)