



---

## *Clarity Check*<sup>TM</sup> Guide for Stago Customers

# Understanding *Clarity Check*<sup>™</sup>

---

## Table of Contents

Table of Contents .....	2
Clarity Check <sup>™</sup> Features & Benefits .....	6
Technical Support .....	6
Error Prevention.....	6
Data.....	7
Reports.....	7
Enrollment Process .....	8
Registration Form .....	8
Contact Information.....	9
Data Submission.....	9
Analyzer Information .....	9
Control Information .....	9
Reagent Information.....	9
Username and Password .....	10
Accessing Clarity Check <sup>™</sup> .....	11
Logging In.....	11
Selecting an Instrument and Instrument ID.....	12
Selecting the Month, Year, and Function .....	13
Lot Setup .....	15
QC Product and Lot Selection .....	15
Adding/Editing Lots.....	16
Online Data Submittal.....	18
Summary Data.....	18
Prompts to Enter Summary Data.....	19
Raw Data .....	20
Prompts to Enter Raw Data .....	21
Reports.....	22
Monthly Summary Report .....	23
Current Month Statistics.....	24

# Understanding *Clarity Check*<sup>TM</sup>

---

Cumulative Statistics .....	24
Peer Group Statistics .....	24
Report Notes .....	24
Histogram .....	25
Youden .....	26
Guidelines for Reviewing Your Reports .....	26
Monthly Summary & STA Unical Reports .....	26
Histogram .....	28
Youden .....	28
Accessing Reports .....	28
Troubleshooting .....	29
Error Messages .....	29
Unavailable Lot .....	30
Incorrect Reports .....	30
Frequently Asked Questions .....	31
Definitions .....	33
Contact Us .....	34

# Introduction

---

## *Welcome to the **Clarity Check™ Online Peer Group Program***

---

The objective of this manual is to help provide a better understanding of the *Clarity Check™* Program. In addition to helping simplify the process, this manual can also be used as a guide to help you properly perform necessary actions.

We are pleased to provide you the following information in this manual:

- Overview
- *Clarity Check™* Benefits
- Enrollment Process
- Accessing Your Account
- Submitting Data
- Reports
- Guidelines for Reviewing Your Reports
- Troubleshooting
- Frequently Asked Questions
- Definitions
- Contact Information

If you have any questions regarding *Clarity Check™*, please feel free to contact Stago Technical Service at 1-800-725-0607.

# Understanding *Clarity Check*<sup>TM</sup>

---

## Overview of *Clarity Check*<sup>TM</sup>

---

*In Stago's continuing effort to provide customers with programs designed to meet the changing needs of the laboratory, we are pleased to offer you our *Clarity Check*<sup>TM</sup> Peer Group Program.*

By enrolling in our peer group program, you have taken the initial steps in establishing practices that will ensure you meet all of the necessary regulatory standards, that your instruments are performing at acceptable levels, and that your laboratory is reporting quality patient results. The second step is to record all of your quality control results on a daily basis. By monitoring your QC and maintaining accurate records, you are able to deter instrument performance issues, as well as prepare your laboratory for future inspections.

*Clarity Check*<sup>TM</sup> is a web-based program that allows instant and flexible data submission as well as on-demand reporting for greater convenience. The real-time database provides up to date peer analysis, which allows for immediate correction action. Large peer comparison groupings provide statistically relevant information and thus insight on PT survey performance. Peer group accuracy through "on the fly" error checking ensures that the peer group is free from erroneous data.

Stago is ready to respond to your changing needs, and we welcome your suggestions. We look forward to working with you to provide the highest quality peer group program for your laboratory.

# Understanding *Clarity Check*<sup>™</sup>

---

## Clarity Check<sup>™</sup> Features & Benefits

### Technical Support

Stago's Technical Support Representatives are available to help you with all steps in the process. From enrolling to printing reports we are here to assist you. Simply call with any questions or concerns.

**Phone:**  
1-800-725-0607

### Error Prevention

Using Patented Error Prevention technology, whenever a value is entered (calculated mean, SD or individual data point) that falls out of the pre-defined range, an error message will be displayed on the screen. This helps to ensure that you are entering your data accurately. Please reference the image on the following page for an example of a 'Validation Message'.

# Understanding *Clarity Check*<sup>TM</sup>

The screenshot displays the Clarity Check web application interface. At the top left is the Clarity Check logo with the tagline 'PEER GROUP PROGRAM FOR STAGO CUSTOMERS'. At the top right is the Stago logo. Below the logos is a navigation menu with 'Home', 'Company Information', 'Products', 'Press Releases', and 'Log Out'. A user profile 'User: Tech Support' is visible in the top right corner. The main content area shows a data entry form for a 'D-Dimer' test. The form includes dropdown menus for 'QC Products' (set to 'STA - Liatest Control N + P') and 'Lots' (set to '109736-1'). A table displays the test results:

Analyte	Unit	Method	Rgt.	Rgt. Lot	Points	Mean	SD	Validation Message	CMean	CSD
D-Dimer	ng/ml	Mechanical	STA - Liatest D-DI		10	2.5	.01	Mean Range:0.000-0.500	0.000	0.000

At the bottom of the form are buttons for 'Edit', 'Submit', 'Cancel', 'Close', and 'Next Lot'. A footer note reads '\*US Patent 7,027,931'.

## Data

*Clarity Check*<sup>TM</sup> automatically calculates Means and Standard Deviations for every Analyte on each lot and level. *Clarity Check*<sup>TM</sup> also automatically converts units of measure. All data can be entered or edited at any time and reports can always be reprinted.

## Reports

All reports are easy to read and can be accessed online at any time. Each report also displays 'Real-Time Peer Group Data'. This ensures that you are viewing the most recent data.

# Understanding *Clarity Check*<sup>™</sup>

---

## Enrollment Process

### Registration Form

Registration is the first step in accessing *Clarity Check*<sup>™</sup>. To obtain a registration form, go to [www.stago-clarity.com](http://www.stago-clarity.com) and click on the 'New Registration' link. The form has the following sections:

- Contact Information
- Data Submission
- Analyzer Information
- Control Information
- Reagent Information

Each of these sections needs to be completed before submitting the registration form. Once processed, you will be contacted with your username and password.

# Understanding *Clarity Check*<sup>™</sup>

---

## Contact Information

- Full name of your Hospital or Laboratory
- Complete mailing address (room number or department, if needed)
- Contact name
- Laboratory phone number
- Contact Email

## Data Submission

- Select data submittal method: via the *Clarity Check*<sup>™</sup> website [www.stago-clarity.com](http://www.stago-clarity.com)
- Starting Month. Please indicate which month you will be beginning to submit data. Typically, this would be the first full month of QC usage after enrolling in *Clarity Check*<sup>™</sup>

## Analyzer Information

- Analyzer Model Name (STA-R/STA-R Evolution Expert Series, STA Compact/CompactMax, STA Satellite, STArt)
- Analyzer Serial Number

## Control Information

- Control Name and Level
- Control Lot Number and Expiration Date

## Reagent Information

- Reagent product name, lot number, and expiration date
- The controls tested
- Unit of measure (seconds, INR, mg/dL, etc...)
- Method for Anti-XA tests
  - Choose Optical Hybrid or Optical Dedicated

# Understanding *Clarity Check*<sup>TM</sup>

## Username and Password

The username and password are what you will need to access your account. The username is a four digit number unique account identifier that is assigned by us for each new customer facility. Since it is not uncommon to have multiple departments within the same facility utilize our service, this adds an extra measure of identification beyond the facility name. The password provides each customer with secure access to their account. After you log into your account, there is an option under 'Setup' that allows the password to be changed.

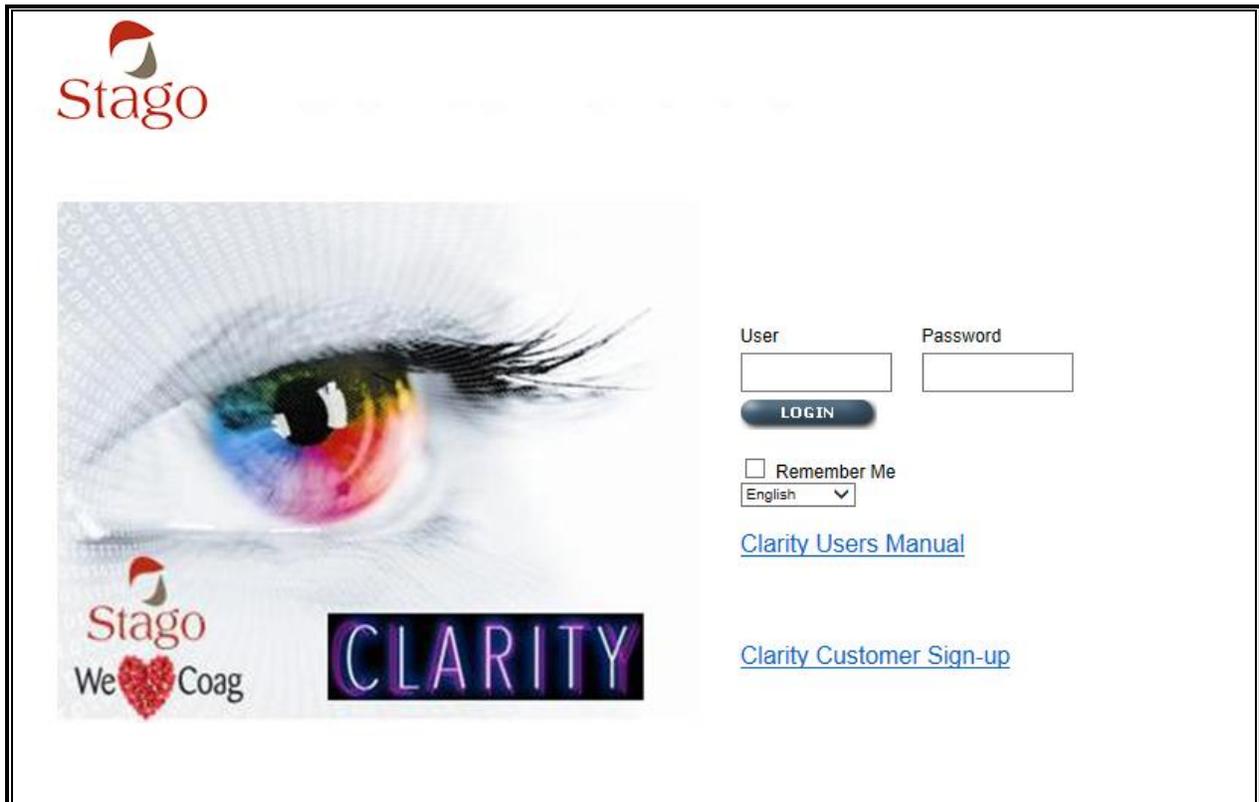
The screenshot displays the Clarity Check web application interface. At the top left is the Clarity Check logo with the tagline "PEER GROUP PROGRAM FOR STAGO CUSTOMERS". At the top right is the Stago logo. Below the logos is a navigation bar with links for Home, Company Information, Products, Press Releases, Log Out, and a language dropdown set to English. The main content area shows user information: DEMO HOSP, 123 Main Street, Anytown MA 01234- U.S.A., STA-R EVO, June 2013, Demo, Monthly QC, and User: Tech Support. A sidebar on the left lists various menu items under categories like Data Entry, Reporting, and Setup. The "Change Password" option is highlighted. The main form area contains three input fields labeled "Old Password:", "New Password:", and "Confirm New:", followed by "Submit" and "Cancel" buttons. A faint world map is visible in the background of the form area. At the bottom left, there is a small text note: "\*US Patent 7,027,931".

# Understanding *Clarity Check*<sup>TM</sup>

## Accessing *Clarity Check*<sup>TM</sup>

### Logging In

In order to gain entry into your account, you must first go to the *Clarity Check*<sup>TM</sup> Login webpage. Here, the program will prompt you to enter your username and password into the appropriate fields. The login page also has a 'Remember Me' checkbox. This feature is available for all customers and can be used by customers that do not want to enter their username each time they log in. For security purposes, the program will still prompt you to enter your password each time. There is also a dropdown menu on the login page where you can select your language preference.



The screenshot shows the Stago Clarity login interface. At the top left is the Stago logo. Below it is a large image of a human eye with a rainbow-colored iris. In the bottom left corner of the image area, there is a smaller Stago logo with the tagline "We ❤️ Coag" and the word "CLARITY" in a stylized font. To the right of the eye image is the login form, which includes:

- Labels for "User" and "Password" above their respective input fields.
- A "LOGIN" button below the input fields.
- A checkbox labeled "Remember Me" below the login button.
- A language dropdown menu currently set to "English" below the "Remember Me" checkbox.
- Two links: "[Clarity Users Manual](#)" and "[Clarity Customer Sign-up](#)".

# Understanding *Clarity Check*<sup>TM</sup>

**CLARITY CHECK**  
PEER GROUP PROGRAM FOR STAGO CUSTOMERS

**Stago**

Home Company Information Products Press Releases Log Out English

DEMO HOSP  
123 Main Street  
Anytown MA 01234- U.S.A.

Select Instrument Model Month Year User: Tech Support

Select Instrument ID Select Function

Data Entry QC Products: QC Product Lots: Lot Numbers

Summary Data  
Raw Data  
Linearity  
Data Import

Reporting  
Monthly Summary  
Linearity  
Trinverical  
Histogram  
Youden  
Search

Setup  
Edit Lot  
New Lot  
Remove Lot  
Change Password

\*US Patent 7,027,931

Welcome to Stago's Clarity™ Peer Group Program.

Follow the prompts below...

- 1) Select the Instrument Model and ID
- 2) Select the month and year
- 3) Select QC or Linearity Material
- 4) Select the product and lot
- 4a) Select the new lot link
- 5) Select a task from the menu to the left

## Selecting an Instrument and Instrument ID

After logging in, the *Clarity Check Check*<sup>TM</sup> welcome page will open. First select the instrument you will be entering data for. This can be found under the dropdown menu labeled 'Select Instrument Model'. In some cases, an account may have more than one instrument to select from (STA-R/STA-R Evolution Expert Series, STA Compact, STA Compact Max, STA Satellite, STArt).

# Understanding *Clarity Check*<sup>TM</sup>

After selecting the instrument, choose the instrument's ID found under the 'Select Instrument ID' pull down menu. Each Instrument ID is established based on information provided on your registration form. This information is used to distinguish between multiple instruments.

The screenshot shows the Clarity Check web application interface. At the top left is the Clarity Check logo with the tagline "PEER GROUP PROGRAM FOR STAGO CUSTOMERS". At the top right is the Stago logo. Below the logos is a navigation bar with links for "Home", "Company Information", "Products", "Press Releases", and "Log Out". The user is logged in as "User: Tech Support". The main content area displays a "Welcome to Stago's Clarity™ Peer Group Program." message with instructions: "Follow the prompts below... 1) Select the Instrument Model and ID, 2) Select the month and year, 3) Select QC or Linearity Material, 4) Select the product and lot, 4a) Select the new lot link, 5) Select a task from the menu to the left". The interface also shows a "Data Entry" section with a "QC Products:" dropdown menu set to "STA-R EVO", a "Select Instrument ID" dropdown menu with options "Demo" and "STA-R", and "Month" and "Year" dropdown menus. A sidebar on the left contains links for "Data Entry" (Summary Data, Raw Data, Linearity, Data Import) and "Reporting" (Monthly Summary, Linearity, Trinivencal, Histogram, Youden, Search). A footer note reads "\*US Patent 7,027,931".

## Selecting the Month, Year, and Function

The Month and Year can be found in the upper right hand corner of the menu, directly under the 'Log Out' link. The Month and Year selected should be for the same month that the QC tests were run. For example, if you ran your samples during the month of May 2008 but did not enter your data until June, you should

# Understanding *Clarity Check*<sup>TM</sup>

change the month so that it reads May. This helps in locating previously entered data much faster. Once the Month and Year are selected, you will have access to the rest of your account. *Clarity Check*<sup>TM</sup> automatically defaults to the function 'Monthly QC'.

**CLARITY CHECK**  
PEER GROUP PROGRAM FOR STAGO CUSTOMERS

Home Company Information Products Press Releases

DEMO HOSP  
123 Main Street  
Anytown MA 01234- U.S.A.

STA-R EVO

Demo

QC Products: STA - Latest Control N + P

Month  
January  
February  
March  
April  
May  
June  
July  
August  
September  
October  
November  
December

Log Out English  
User: Tech Support

2013

36-1

**Welcome to Stago's Clarity<sup>TM</sup> Peer Group Program.**

**Follow the prompts below...**

- 1) Select the Instrument Model and ID
- 2) Select the month and year
- 3) Select QC or Linearity Material
- 4) Select the product and lot
- 4a) Select the new lot link
- 5) Select a task from the menu to the left**

\*US Patent 7,027,931

# Understanding *Clarity Check*<sup>TM</sup>

## Lot Setup

### QC Product and Lot Selection

The screenshot displays the Clarity Check web application interface. At the top left is the Clarity Check logo with the tagline "PEER GROUP PROGRAM FOR STAGO CUSTOMERS". At the top right is the Stago logo. Below the logos is a navigation bar with links for Home, Company Information, Products, Press Releases, Log Out, and a language dropdown set to English. The user is identified as "User: Tech Support".

The main content area shows the "Lot Setup" process. On the left is a vertical menu with options: Data Entry (Summary Data, Raw Data, Linearity, Data Import), Reporting (Monthly Summary, Trinivertical, Histogram, Youden, Search), and Setup (Edit Lot, New Lot, Remove Lot, Change Password). The "QC Products" dropdown is set to "STA - Liatest Control N + P". The "Lots" dropdown is open, showing "109736-1" and "109736-2".

Centered on the page is a welcome message: "Welcome to Stago's Clarity<sup>TM</sup> Peer Group Program. Follow the prompts below...". Below this is a numbered list of instructions:

- 1) Select the Instrument Model and ID
- 2) Select the month and year
- 3) Select QC or Linearity Material
- 4) Select the product and lot
- 4a) Select the new lot link
- 5) Select a task from the menu to the left**

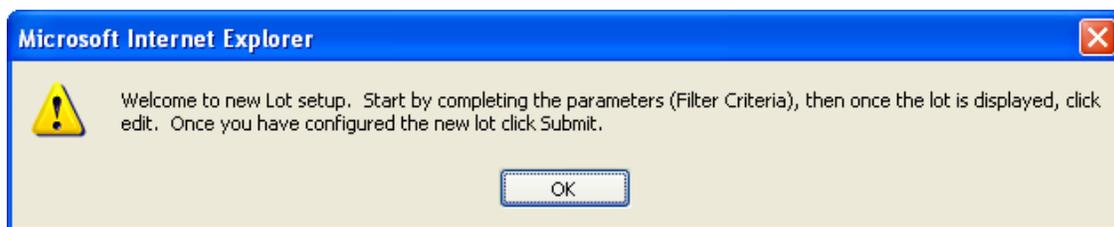
At the bottom left, there is a small text: "\*US Patent 7,027,931". On the right side, there is a faint map of Europe.

After the instrument and date information have been selected, select the correct product from the 'QC Product' dropdown menu. Each QC Product is listed by name, level, and is linked to the 'Lots' dropdown menu. For example, if the QC Product Liatest Control N + P is selected, only Liatest Control N + P lots will be available for selection. If the lot needed is not an available option, you will need to add a lot to your account (please see the section for Adding/Editing lots for help on this function). Once a lot is selected, you are now ready to start entering data.

# Understanding *Clarity Check*<sup>TM</sup>

---

## Adding/Editing Lots



The welcome message listed above will pop up after the 'Add Lot' link is selected. This gives you brief instructions on how to add a new lot. To bypass this message, you can simply click 'OK'.

Next, choose the new QC Product and Lot Number found in the dropdown menus labeled 'QC Products' and 'Lots'. Listed at the middle bottom of the page there are four options: Edit, Submit, Cancel, and Close. Only Edit and Cancel are highlighted as options. In order to add a lot click 'Edit'. Once in this mode select all the appropriate Analytes, Reagents, and Reagent Lots. Select the Method 'Optical' or 'Mechanical'.

To select an Analyte check the box to the left of the Analyte column. To select a Reagent, simply click on the dropdown menu listed under 'Rgt.' and pick the correct Reagent. Each lot listed in the 'Rgt Lot' is linked to the corresponding Reagent. For all instruments, a Method must be selected. After all necessary criteria have been selected; you must click 'Submit' for the program to save any new lot information.

# Understanding *Clarity Check*<sup>TM</sup>

**CLARITY CHECK**  
PEER GROUP PROGRAM FOR STAGO CUSTOMERS

Stago

Home Company Information Products Press Releases Log Out English

DEMO HOSP STA-R EVO July 2013 User: Tech Support  
123 Main Street Demo Monthly QC  
Anytown MA 01234- U.S.A.

Data Entry QC Products: STA - Liatest Control N + P Lots: 109738-1

	Analyte	Description	Unit	Method	Rgt.	Rgt. Lot
<input type="checkbox"/>	vWFA	vWF Activity	%			
<input type="checkbox"/>	FPro	Protein S Antigen (Free)				
<input checked="" type="checkbox"/>	D-Dimer	D-Dimer	ng/ml	Mechanical	STA - Liatest D-C	

\*US Patent 7,027,931

Edit Submit Cancel Close

To edit an existing lot, click the 'Edit Lot' link on the left hand side of the page, under setup. This section is where all lot information is updated. However, if data has already been entered for the selected lot and the selected Month and Year, the Analytes containing data will not be accessible. If no data has been entered, follow the same steps as adding a lot. All necessary criteria should be selected before hitting 'Submit'.

# Understanding *Clarity Check*<sup>TM</sup>

---

## Online Data Submittal

*There are three different methods available to submit Monthly QC data Online. The first option is to enter your calculated Mean and SD QC results. The second is to enter each individual QC sample result. These are referred to as Summary and Raw Data entry respectively. Each of these options will be explained in detail in this section.*

## Summary Data

Customers that have the ability to accurately calculate their mean and standard deviations are recommended to use Summary Data. Here, enter the number of points (QC Samples run during the selected Month) as well as the calculated mean and calculated 1 standard deviation.\*

**\*Please reference the example of how to enter Summary Data on page 20.**

# Understanding *Clarity Check*<sup>TM</sup>

---

## Prompts to Enter Summary Data

1. Click the 'Summary Data' link found on the left side of the page under Data Entry.
2. Verify the selected QC Product and Lot are correct.
3. Click Edit located in the bottom center of the page.
4. Place cursor in the text box under 'Points' for the first Analyte.
5. Enter the number of data points.
6. Use the <Tab> key to advance into the 'Mean' field.
7. Enter the calculated monthly mean for the selected Analyte.
8. Use <Tab> again to advance into the 'SD' field.
9. Enter the calculated monthly 1 standard deviation for the selected Analyte.
10. Use <Tab> again to advance to the next Analyte, if applicable.
11. Repeat steps 5-10 until all data for selected lot is completely entered.
12. Verify all points, means, and standard deviations have been entered correctly for all Analytes.
13. Click 'Submit' located at the bottom center of the page in order to save all values entered.
14. Repeat this process for all lots before attempting to print reports.

# Understanding *Clarity Check*<sup>TM</sup>

The screenshot displays the Clarity Check web application interface. At the top left is the Clarity Check logo with the tagline "PEER GROUP PROGRAM FOR STAGO CUSTOMERS". At the top right is the Stago logo. Below the logos is a navigation menu with "Home", "Company Information", "Products", and "Press Releases". A "Log Out" button and a language dropdown set to "English" are also present. The user is identified as "User: Tech Support".

The main content area includes a form for data entry. It features dropdown menus for "STA-R EVO", "July", "2013", "Demo", and "Monthly QC". Below these are fields for "QC Products" (set to "STA - Liatest Control N + P") and "Lots" (set to "109738-1").

A table displays the entered data:

Analyte	Unit	Method	Rgt.	Rgt. Lot	Points	Mean	SD	Validation Message	CMean	CSD
D-Dimer	ng/ml	Mechanical	STA - Liatest D-DI		10	.25	.02		0.000	0.000

On the left side, there is a "Data Entry" menu with links for "Summary Data", "Raw Data", "Linearity", "Data Import", "Reporting", "Monthly Summary", "Linearity", "Trinivertical", "Histogram", "Youden", "Search", "Setup", "Edit Lot", "New Lot", "Remove Lot", and "Change Password". At the bottom, there are buttons for "Edit", "Submit", "Cancel", "Close", and "Next Lot". A copyright notice "\*US Patent 7,027,931" is visible in the bottom left corner.

## Raw Data

Raw Data is recommended for customers who do not have the capability to calculate their means or standard deviations. Additionally, entering individual points provides a cleaner and more accurate peer group. This option requires only the individual result values be entered into the *Clarity Check*<sup>TM</sup> Program. The system will automatically calculate the number of points, mean and standard deviations. The 'Raw Data' link is also found on the left under Data Entry.\*

# Understanding *Clarity Check*<sup>™</sup>

---

## Prompts to Enter Raw Data

1. Click the 'Raw Data' link found on the left side of the page under Data Entry.
2. Verify the selected QC Product and Lot are correct.
3. Click Edit located in the bottom center of the page.
4. Verify the correct Analyte, which is located to the left of the Value column, is selected.
5. Place cursor in the first field under the 'Value' column.
6. Enter the first data point.
7. Use the <Tab> key to advance to the next field.
8. Repeat steps 6 and 7 until all data points are entered for the selected Analyte.
9. If applicable, select the next Analyte by clicking on it.
10. Repeat steps 5-9.
11. After all data points have been entered for all Analytes, click 'Submit' located at the bottom center of the page in order to save all values entered.
12. Repeat this process for all lots before attempting to print reports.

**\*Please reference the example on page 22**

# Understanding *Clarity Check*<sup>TM</sup>

The screenshot displays the CLARITY CHECK web application interface. At the top left is the CLARITY CHECK logo with the tagline "PEER GROUP PROGRAM FOR STAGO CUSTOMERS". At the top right is the Stago logo. Below the logos is a navigation bar with links: Home, Company Information, Products, Press Releases, Log Out, and a language dropdown set to English. The user is identified as "User: Tech Support".

The main content area shows a data entry form for a QC product. The "QC Products" dropdown is set to "STA - Liatest Control N + P" and the "Lots" dropdown is set to "109736-2". The form includes a table with the following data:

Analyte	Unit	Method	Rgt.	Rgt. Lot	#	Value	Validation Message
D-Dimer	ng/ml	Mechanical	STA - Liatest D-DI		1	2.2	
					2	2.3	
					3	2.3	
					4	2.4	
					5	2.6	
					6	2.1	
					7	2.0	
					8	2.4	x

Below the table, the statistics are displayed: "C Mean: C SD: 2SD High: 2SD Low:" and "Points: 8 Mean: 2.287 SD: 0.18". At the bottom of the form are buttons for "Edit", "Submit", "Cancel", "Close", and "Next Lot".

On the left side of the interface, there is a "Data Entry" menu with links for Summary Data, Raw Data, Linearity, Data Import, Reporting, Monthly Summary, Linearity, Trivariate, Histogram, Youden, Search, Setup, Edit Lot, New Lot, Remove Lot, and Change Password. At the bottom left, there is a note: "\*US Patent 7,027,931".

## Reports

The reports listed below are available to Stago customers. Each report displays the customer's address, Analyzer, and lot information as well as is a unique representation of the data submitted.

- STA Unical Report
- The Monthly Lab Summary Report
- The Histogram Report
- The Youden Report

# Understanding Clarity Check™

## Monthly Summary Report

The Monthly Summary Report summarizes your monthly statistics as well as your peers. The Monthly Summary Report displays the Current, Cumulative, and Peer Group Statistics. These three sections are broken down by the column headers listed below:

- Number of data points submitted
- Calculated Mean\*
- Calculated SD\*
- Calculated 2SD Range\*
- CV%\*
- SDI\*

\*Please reference Definitions on page 33.



DEMO HOSP  
123 Main Street  
  
Anytown  
MA 01234- U.S.A.  
Attn : Test Lab

**ReliantC Lab Summary Report**  
Report Period : June 2013  
Data Submitted: Monthly Summary Data

Instrument ID: Demo  
Instrument Model: Expert Series  
Serial Number:  
QC Lot #    QC Product  
109736    STA - Liatest Control N + P  
109736    STA - Liatest Control N + P

Level	Lot #	June 2013 Statistics						June 2013 Peergroup Data All Stago Analyzers					Cumulative Statistics					Cumulative Peer Statistics All Stago Analyzers							
		Acc	N	Rej	Mean	SD	CV %	SDI	Lab	Mean	SD	CV %	CVI	N	Mean	SD	CV %	SDI	Lab	Mean	SD	CV %	CVI		
D-Dimer	Mechanical	STA - Liatest D-DI																							
1	109736	12			0.40	0.02	3.75	1.08	2	0.30	0.09	30.94	0.12	22	0.33	0.08	23.60	0.55	2	0.29	0.08	28.85	0.13		
2	109736	12			2.00	0.05	2.50	-0.61	2	2.11	0.18	8.59	0.29	12	2.00	0.05	2.50	-0.61	2	2.11	0.18	8.59	0.29		

**Notes :**

- "Rej" are the number of test values in excess of  $\pm 3SD$  from your laboratory mean that have been excluded from statistical calculations. To identify the individual values, review your QC for the month.
- Only those lots for which the current month data has been submitted are included in the summaries.
- Highlighted data indicates that either the Mean or SD value is outside of the ReliantC predetermined ranges. This data has been excluded from the peergroup. Please review your data. You may resubmit all corrected data within 30 days to receive an updated report.
  - This applies to the entire summarized data set. If the calculated Mean or SD for the given month is outside of the predetermined ranges, the entire data set is excluded from all peer group calculations.
  - Please establish your own ranges and use manufacturer ranges as a guide.
- SDI values above or below  $\pm 2$  should be reviewed for accuracy against the peergroup.

Tcoag US Inc. 5 Century Drive Parsippany, NJ 07054 Tel: 888-291-0415  
Copyright © 2007 Bionostics

Page 1 of 1  
Printed On: August 01, 2013

# Understanding *Clarity Check*<sup>™</sup>

---

## Current Month Statistics

The Current Month Statistics sections, displayed as 'Month/Year Statistics', contains the data that was submitted for each lot, level, and Analyte for the specific month displayed.

## Cumulative Statistics

The Cumulative Statistics section displays the lot-to-date statistics for all data ever submitted for the specific lots and Analytes displayed.

## Peer Group Statistics

The data displayed in the Peer Group Statistics is a summary of all data submitted by other customers using the same lot and similar instrumentation.

## Report Notes

# Understanding *Clarity Check*<sup>™</sup>

---

The Monthly Summary contains the Report Notes listed below. These notes help to explain how each report is summarized.

1. "Rej." are the number of test values in excess of  $\pm 3$  SD from your laboratory mean that have been excluded from statistical calculations. To identify the individual values, review your QC for the month.
  - a. *This details the number of individual data points that were deemed as outliers and excluded from the calculated statistics.*
  - b. *This section only applies to customers that submitted raw data online or via the Levy-Jennings charts. This does not apply to customers who submitted summarized data.*
2. Only those lots for which the current month data has been submitted are included in the summaries.
  - a. *All prior lot information is still retained and can be retrieved by re-running historical reports.*
3. **Highlighted** data indicates that either the Mean or SD value is outside of Clarity Check<sup>™</sup> predetermined ranges. This data has been excluded from the peer group. Please review your data. You may resubmit all corrected data within 30 days to receive an updated report.
  - a. *This applies to the entire summarized data set. If the calculated Mean or SD for the given month is outside of the predetermined ranges, the entire data set is excluded from all peer group calculations.*
  - b. *Please establish your own ranges and use manufacturer ranges as a guide.*
4. SDI values above or below  $\pm 2$  should be reviewed for accuracy against the peer group.

## Histogram

# Understanding *Clarity Check*<sup>TM</sup>

---

The Histogram Report is a comparison to your peer group over several months. The I-bar represents the  $\pm 2SD$  of your peer group mean and the circle represents your monthly mean.

## Youden

The Youden Report is a plotted graph which compares your Level 1, Level 2, and/or Level 3 summarized Monthly QC data to your peer group. The center of the plot represents the group mean when Level 1 results are plotted against Level 2 (or 3) results. The circles represent your peers and the triangle represents your laboratory mean. The closer your triangle is to the center of the graph represents that your laboratory is reporting in line with your peers.

## Guidelines for Reviewing Your Reports

### Monthly Summary & STA Unical Reports

- **Review** the current month's Mean to verify it has not changed significantly from the cumulative mean for your laboratory. A significant shift may indicate performance issues. Compare the current month's mean to the peer group mean.
- **Review** the **SD**. The standard deviation is related to the spread or distribution of control results about the expected **Mean**. Whereas the mean is an indicator of central tendency and therefore related to accuracy or systematic error, the standard deviation is a measure of the width of the distribution and is related to imprecision or random error. The wider the standard deviation range is, the poorer the precision of the method and vice versa.

## Understanding *Clarity Check*<sup>™</sup>

---

- If a single data point falls outside the **+/- 2SD** range, it may be a warning that there was a problem with an individual control material, or control testing event. Laboratories use this as an indication to verify the results to determine if the problem was instrument or operator related. This is known as the **1<sub>2s</sub>** or **Warning rule** in the **Westgard Multi-rules**. If the second value falls outside the **2SD** range, further corrective action should be initiated.
- **Review** the **CV** of all levels of control analyzed. The **CV**'s should be within the same relative range each month. A **CV** of 5.0% or less is an acceptable level of variation indicating a well-functioning system.
- **CV** of the cumulative data is the best indication of the long-term performance of your analyzer. A substantial difference between the monthly **CV** and the cumulative **CV** may indicate a trend or gradual change in the mean values on a particular level over time.
- **Review** the **SDI** calculated for the month. Proficiency testing results are based on the precision of the peer group reporting to the group. An **SDI** between -2.0 and +2.0 indicates good correlation with the peer group. A negative sign indicates that your laboratory mean is below the peer group mean, a positive sign indicates that your laboratory mean is above the peer group mean.
- **SDI** of the cumulative data is a good indicator of prospective proficiency test performance. A substantial difference between the current month **SDI** and the cumulative **SDI** may indicate a change in the performance of your analyzer over time.
- Individual instrument Mean should be within **2SD** of the peer group for best correlation and prediction of proficiency performance.
- Peer group **SD** and **CV** numbers may be higher than the individual instrument statistics because of variations in instrument operating conditions.
- The **CVI** is the relative **CV** of the individual instrument compared to the peer group **CV**. The **CVI** should be less than 1.0.

# Understanding *Clarity Check*<sup>™</sup>

---

## Histogram

Verify that your laboratory mean lies between the extremes of the I-bar. For a normal distribution, 95.5% of all the peers reporting should be within a **2SD** of the peer mean. If a single data point falls outside the **+/- 2SD** range, it may be a warning that there was a problem with an individual control material, or control testing event. Laboratories use this as an indication to verify results to determine if the problem was instrument or operator related. This is known as the  $1_{2s}$  or **Warning rule** in the **Westgard Multi-rules**. If the second value falls outside the **2SD** range, further corrective action should be initiated. Contact Stago Technical Support if there is a trend or if your mean is outside the range.

## Youden

**Review** and verify that your data (the triangle) is within the **2SD** box. For a normal distribution, 95.5% of your peers reporting should be within **2SD** of the group peer mean. Contact Stago Technical Services if your laboratory mean does not fall within the **2SD** box for two consecutive months.

## Accessing Reports

You have the ability to access your reports immediately after submitting data by clicking links located under Reporting. Once a link is clicked, a peer report will be generated for all lots containing data on the instrument selected.

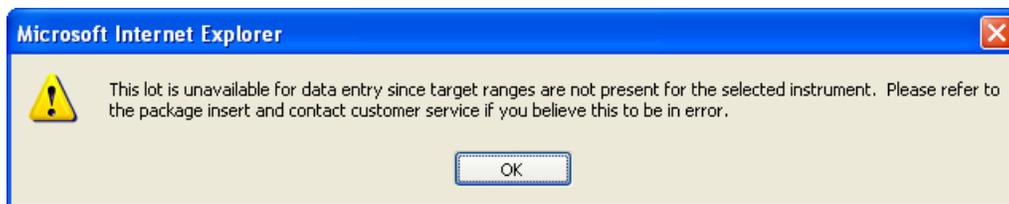
# Understanding *Clarity Check*<sup>TM</sup>

---

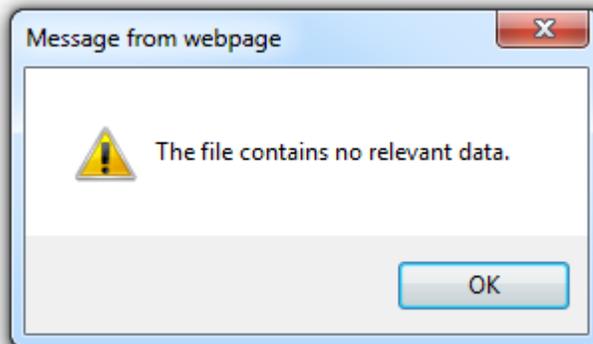
## Troubleshooting

### Error Messages

The following message will display if ranges have not yet been entered into our system or if the lot set up is incorrect.

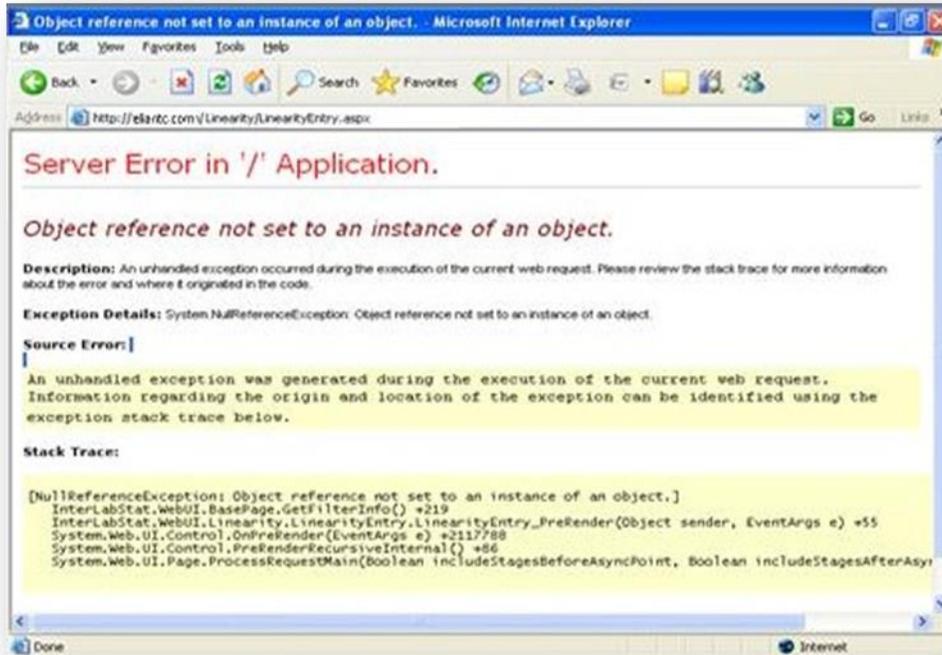


The following message will display if the data within the file does not match the analyzer, date, or lot information selected.



# Understanding *Clarity Check*<sup>TM</sup>

The following error message generates when a page on *Clarity Check*<sup>TM</sup> is not fully loaded. Simply click the refresh button and *Clarity Check*<sup>TM</sup> will bring you back to the previous page.



## Unavailable Lot

If your specific lot number is not an available selection under the 'Lots' dropdown menu, click the 'New Lot' link found under 'Setup' on the left hand side of the page. If your lot is not listed in the new lot sections, confirm that you have selected the proper product and if you still can't locate it, please call our Technical Support Representatives.

## Incorrect Reports

Please call our Technical Support Representatives if there is an error on your report and a revised report will be mailed, emailed, or faxed.

# Understanding *Clarity Check*<sup>TM</sup>

---

## Frequently Asked Questions

**Q:** *When should I submit my data?*

**A:** Customers that enter your data online are advised to enter your data by the 10<sup>th</sup> of each month. However, data can be entered online at any time.

**Q:** *How do I add/remove an instrument?*

**A:** To add or remove any instruments from your account, please call our Technical Support Representatives to make this update.

**Q:** *How do I add new lot numbers to my online account?*

**A:** Select the 'New Lot' link located under Setup on the left-hand side of the page. Select your QC product name. Select your New Lot number found under the Lots pull-down menu. Click the Edit button at the bottom of the menu. Click the checkbox to select the necessary Analytes. Click the 'Submit' button at the bottom of the page to save.

**Q:** *How do I add additional or missing Analytes to my Clarity Check<sup>TM</sup> online account?*

**A:** Once you've selected the appropriate lot number, click the 'Edit Lot' link located under Setup on the left-hand side of the page. Click the Edit button at the bottom of the menu. Check off the checkbox to add additional Analytes. Click the Submit button at the bottom of the page to save.

**Q:** *When I click a link under 'Reporting' nothing happens. Why isn't my report generating?*

**A:** This issue typically occurs when a pop-up blocker is active. Immediately after clicking on a report, if a message doesn't appear, check the top of

## Understanding *Clarity Check*<sup>TM</sup>

---

your menu for a yellow-orange box with a “⊗”. When you hold the cursor over this bar the message “Pop-up blocked” will appear. Right-click on the Pop-Up message and then select: ‘*Always allow Pop-Up on this site*’. Do not select ‘*Temporarily remove Pop-Up*’, as you will be accessing these reports frequently.

**Q:** *How do I fix an error in my report?*

**A:** Customers that submit data online can edit data up to five years old by logging into your account and making the necessary correction(s). After clicking ‘Submit’, a revised report can be printed.

**Q:** *I keep receiving ‘Session Expired’ error when I try to enter my data.*

**A:** There is a security feature built into the site that will automatically expire the session if there has been a long period of inactivity on the page. If this happens regularly, without any extended period of inactivity, contact your IT department to see if there is an issue on your end. Typical causes include loss of internet connection as can be caused by power failure, network maintenance, cabling issues, etc.

**Q:** *I get the error message ‘Server Error in '/' Application.’ when I try to enter my data.*

**A:** This error generally occurs if you have lost connection to the site. Close your browser and try to re-entering the site. If the trouble persists, please contact our Technical Support Representatives for further troubleshooting.

**Q:** *I get the error message ‘No Relevant Data’ when I try to import my data file.*

**A:** This error generally occurs if the incorrect data or analyzer is selected. Verify analyzer and date selected is listed in the file and retry. If the trouble persists, please contact our Technical Support Representatives for further troubleshooting.

# Understanding *Clarity Check*<sup>™</sup>

---

## Definitions

<b>Mean</b>	Returns the average (arithmetic mean) of all accepted test values.
<b>SD</b>	Standard Deviation. Measures the distribution of test values around the mean. In a normal distribution, 68% of all values fall within a one standard deviation (1 SD) range, 95.5% within a 2 SD range and 99.7 within a 3 SD range.
<b>2SD Range</b>	The range is calculated by multiplying the standard deviation (SD) by two, then subtracting it from the mean to get the minimum range value and adding it to the mean to arrive at a maximum range value. Often used to establish quality control limits.
<b>Standard Deviation Index</b>	The Standard Deviation Index (SDI) measures the relative accuracy of a result on one instrument to the precision of the test methodology (peer group).
<b>Coefficient of Variation (CV%)</b>	Coefficient of variation (CV%) provides a measure of precision expressed as a percentage of the standard deviation (SD) in relation to the mean. CV% facilitates comparison of precision between different levels.
<b>Coefficient of Variation Index (CVI)</b>	The Coefficient of Variation Index provides a comparative measure of system imprecision relative to that of group imprecision.

# Understanding *Clarity Check*<sup>™</sup>

---

## Contact Us

Listed below is the contact information for Stago. Please feel free to contact us with any comments, questions, or concerns.

**Phone:**

1-800-725-0607