TECHNOPATH
CLINICAL DIAGNOSTICS

THE QUALITY CONTROL COMPANY

IAMQC®

Guide to **Reagent Lot Reports**

AUTOMATED REPORTS IN IAMQC PEER

Contents

Introduction

Importance of reagent lot tracking

In the clinical laboratory the verification of new reagent lot performance is a common task. It is considered good laboratory practice, and further laboratory regulations and accreditation standards require the evaluation of each new reagent lot prior to use [1,2].

Lot-to-lot variation affecting calibrators and reagents is a frequent challenge that can affect the laboratory's ability to produce consistent results over time. It is important that laboratories have procedures in place for quantification of this variability, and for determining whether the amount of variation is acceptable for the release of patient results. Clinically significant "lot-to-lot variability", when undetected, can cause changes in results which may present a risk to patient care[3].

"Differences between reagents and testing systems are known to contribute to test result variability, making crossover studies necessary when using new reagents or implementing new testing systems."[4]

In the clinical laboratory, immunoassays have been reported to be more prone to lot-to-lot variability than general chemistry tests. This is particularly critical when an analyte is used for long-term follow-up of patients, as in the case with tumor markers, when small changes in concentration may trigger further laboratory testing, imaging, or other clinical interventions[1].

It is important to note that the IVDR[5] (In Vitro Diagnostic Regulation) and CAP[6] (College of American Pathologists) require information regarding batch-to-batch variation be provided with relevant figures and units of measure. In practice, there may be significant differences between individual reagent lots. This is precisely where the control material, which has not been optimized for the single reagent lot, is required as an independent review of the analytical process[7].

Sources of reagent lot variability

Possible causes of a change in performance with a new reagent lot include changes or instability in reagent component materials, compromising of reagents in transportation or storage, and incorrect calibration of the new reagent lot.

Reagent lot tracking in practice

Reagent lot-to-lot testing varies widely among clinical laboratories. Variation can affect the QC results, patient results or both. "There are no universally agreed upon acceptance or rejection criteria for new reagent lots. It is up to the laboratory management to determine what is acceptable."[1]

It is important to undertake an internal quality control process using QC materials that closely mimic human samples[3] and for which a significant interlaboratory Peer comparison is available[3]. Technopath's Multichem® independent quality control materials supported by our IAMQC® QC data management software supports the clinical laboratory in this regard.

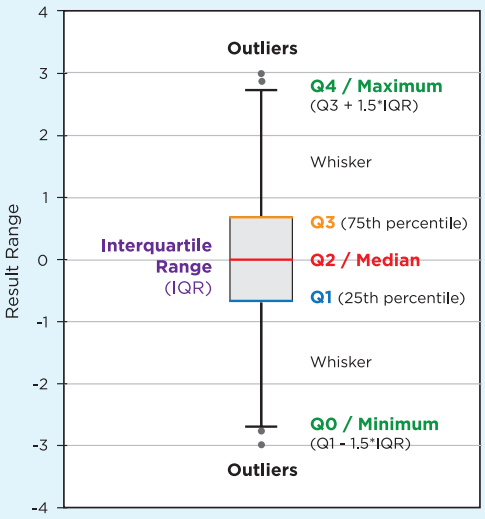
Getting Started

To further support the clinical laboratory in the automating the tracking and reporting of reagent lot to lot variation, Technopath now presents the new "Reagent Lot Report".

Please contact our **QCSoftware@technopathcd.com** with your IVD instrument details to arrange set up.

A Note on Box Plots

A boxplot is a standardized way of displaying the dataset based on a five-number summary: the minimum, the maximum, the sample median, and the first and third quartiles.



Example of reagent lot boxplot showing position of outliers.

The boxplot is constructed of two parts, a box and a set of whiskers shown in this figure. The lowest point is the minimum of the data set and the highest point is the maximum of the data set. The box is drawn from Q1 to Q3 with a horizontal line drawn in the middle to denote the median.

Q4 / Maximum (100th percentile): the largest data point excluding any outliers.

Q3 / Third quartile (75th percentile): also known as the upper quartile, is the median of the upper half of the dataset.

Q2 / Median (0th percentile): the middle value of the dataset.

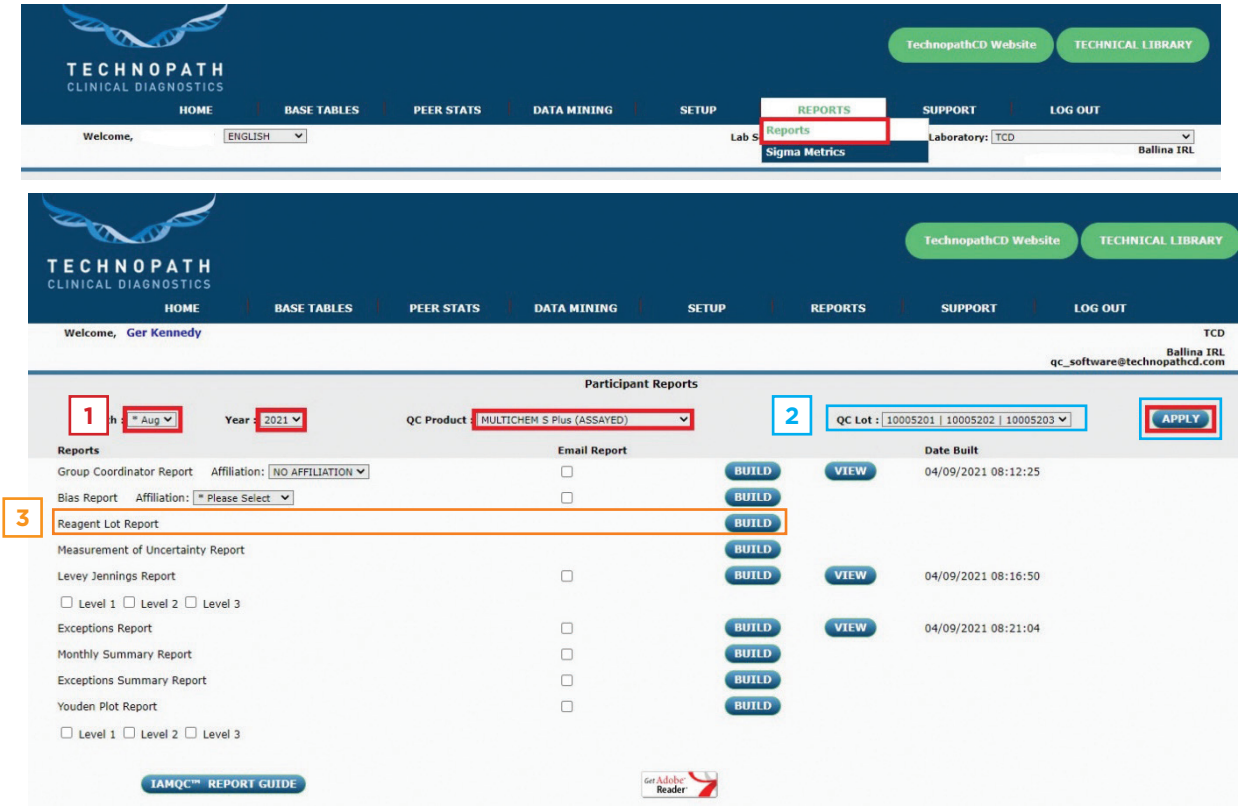
Q1 / First quartile (25th percentile): also known as the lower quartile, is the median of the lower half of the dataset.

Q0 / Minimum (0th percentile)**:** the lowest data point excluding any outliers.

IAMQC® reagent lot report overview

Building a Reagent Lot Report

The reagent lot report provides peer statistics broken out by reagent lot for each assay on the instruments in the lab for the chosen QC lot number. The reagent lot report is accessed in the Reports area of the system:



1 Select month, year and product from the drop down menus and select APPLY.

2 Select the relevant QC lot number from the drop down menu and select APPLY to confirm the lot number you wish to generate the report for.

3 Select BUILD opposite “Reagent Lot Report” to generate the report in Microsoft Excel format.

Structure of the Reagent Lot Report Explained

A Note on Report Format

The report will be available as a Microsoft Excel file and will include the following headings:

- **Analyte:** This is the selected reagent analyte being reported
- **Reagent lot:** Reagent lot number being reported
- **Level:** Level of QC
- **Units:** Unit of measurement of the analyte being reported
- **Source:** World Peer Lot to Date, World Peer or Instrument Serial Number
- **#inst:** The number of instruments contributing to the peer calculation
- **N:** The number of data points
- **Mean:** Average
- **SD:** Standard Deviation
- **%CV:** Percentage Cumulative Value
- **Min:** The lowest data point excluding any outliers
- **Max:** The highest data point excluding any outliers
- **Median:** the middle value of the dataset
- **Q1:** First quartile (25th percentile): also known as the lower quartile, is the median of the lower half of the dataset.
- **Q3:** Third quartile (75th percentile): also known as the upper quartile, is the median of the upper half of the dataset.

The data is displayed in tabular format listed by analyte with the first rows on the table showing the world peer lot-to-date (LTD) values for results using the stated reagent lot number.

The following example table shows the lot-to-date peer values for Alanine Aminotransferase for two reagent lots for three levels of QC material:

Analyte	Reagent lot	Level	Units	Source	#Inst	N	Mean	SD	%CV	Min	Max	Median	Q1	Q3
AFP	Reagent Lot 1	1	ng/mL	World Peer LTD	59	1549	6.024	0.053	0.877					
AFP	Reagent Lot 1	2	ng/mL	World Peer LTD	57	1590	72.476	0.271	0.374					
AFP	Reagent Lot 1	3	ng/mL	World Peer LTD	53	1508	187.428	1.058	0.565					
AFP	Reagent Lot 2	1	ng/mL	World Peer LTD	17	513	6.094	0.029	0.474					
AFP	Reagent Lot 2	2	ng/mL	World Peer LTD	17	534	72.045	0.125	0.174					
AFP	Reagent Lot 2	3	ng/mL	World Peer LTD	17	512	185.117	1.374	0.742					
AFP	Reagent Lot 1	1	ng/mL	World Peer	44	672	5.980	0.248	4.151					
AFP	Reagent Lot 1	2	ng/mL	World Peer	44	654	72.234	2.337	3.235					
AFP	Reagent Lot 1	3	ng/mL	World Peer	41	637	187.347	7.110	3.795					
AFP	Reagent Lot 2	1	ng/mL	World Peer	17	496	6.092	0.158	2.601					
AFP	Reagent Lot 2	2	ng/mL	World Peer	17	517	72.051	1.488	2.065					
AFP	Reagent Lot 2	3	ng/mL	World Peer	17	494	185.048	3.348	1.809					
AFP	Reagent Lot 1	1	ng/mL	Instrument 1	1	19	5.767	0.104	1.810	5.620	5.930	5.780	5.670	5.850
AFP	Reagent Lot 1	1	ng/mL	Instrument 2	1	14	5.897	0.105	1.778	5.730	6.080	5.920	5.810	5.970
AFP	Reagent Lot 1	2	ng/mL	Instrument 1	1	20	70.194	1.180	1.681	67.510	72.220	70.270	69.480	71.020
AFP	Reagent Lot 1	2	ng/mL	Instrument 2	1	14	72.809	1.958	2.690	70.150	77.360	72.290	71.510	73.940
AFP	Reagent Lot 1	3	ng/mL	Instrument 1	1	24	179.199	3.124	1.743	173.960	186.050	179.690	176.590	180.970
AFP	Reagent Lot 1	3	ng/mL	Instrument 2	1	13	185.001	4.228	2.285	177.310	192.340	184.420	182.340	187.460
AFP	Reagent Lot 2	1	ng/mL	Instrument 1	1	26	5.975	0.325	5.438	4.620	6.410	5.990	5.870	6.170
AFP	Reagent Lot 2	1	ng/mL	Instrument 2	1	29	6.007	0.123	2.041	5.680	6.180	6.010	5.950	6.100
AFP	Reagent Lot 2	2	ng/mL	Instrument 1	1	20	71.813	1.811	2.522	69.320	75.560	71.690	69.960	72.950
AFP	Reagent Lot 2	2	ng/mL	Instrument 2	1	28	71.387	1.651	2.313	67.780	74.090	71.400	69.930	72.640
AFP	Reagent Lot 2	3	ng/mL	Instrument 1	1	23	184.743	3.477	1.882	178.390	190.510	184.830	182.300	188.220
AFP	Reagent Lot 2	3	ng/mL	Instrument 2	1	30	182.986	3.888	2.125	175.880	188.200	182.990	179.010	186.540

The rows in the table are colour coded to represent:

1 **World Peer LTD** - Current World Peer Lot To Date. The rows highlighted in purple show the lot to date peer value for the reagent lot for each level. This is inclusive of all values submitted for that lot to date.

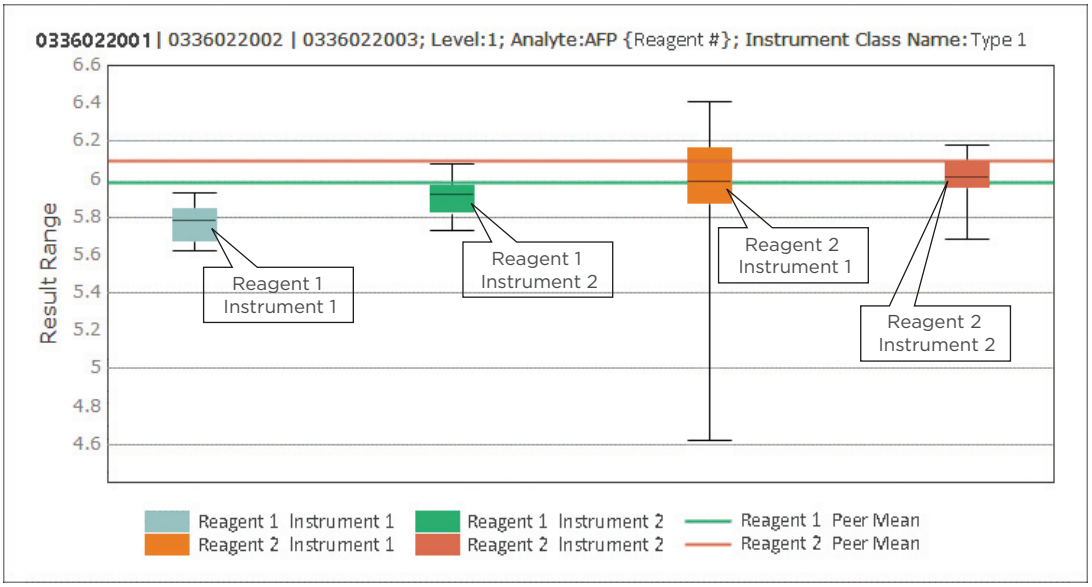
2 **World Peer** - Lot mean month to date. The same information as described for the lot to date values are shown for the current month peer also.

3 **Data for each individual instrument** in the lab is then displayed showing the following:

- Instrument serial number

- Number of data points on each instrument for the reagent lot number
- Mean, SD, CV% calculations
- Minimum value submitted for that lot/level on that instrument for that reagent lot
- Maximum value submitted for that lot/level on that instrument for that reagent lot
- Median value for that lot/level on that instrument for that reagent lot
- Quartile 1 and Quartile 3 values calculated based on the data submitted. These are used to position the box plot on the graph

Using this information, a box plot is generated to show the spread of values across the range for each instrument and reagent lot. Each level of QC is shown on a different chart and the current month world peer value is displayed as a line on the chart for each reagent lot:



This provides the lab with a view of performance on the same QC lot but across the various reagent lots used in the lab in that month.

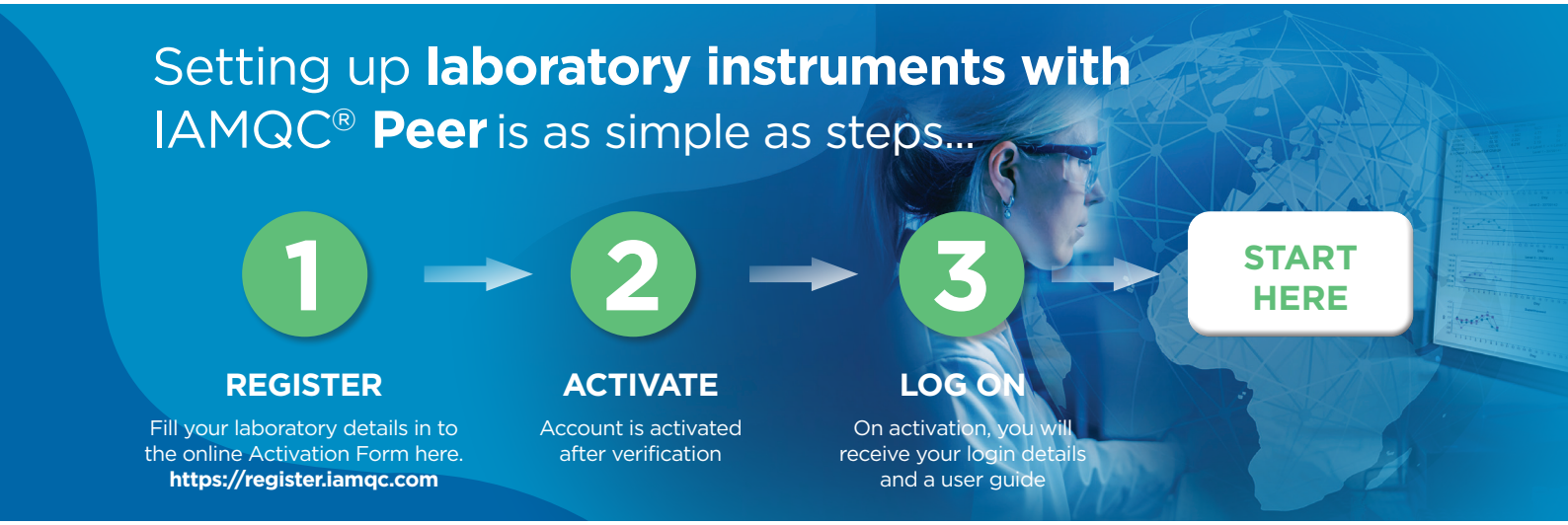
The report will contain entries for all analytes where data was submitted for the month and QC lot selected.

Request IAMQC® PEER Demo:
iamqcsupport@technopathcd.com

Full Suite of Reports with IAMQC®

IAMQC Peer contains the following reports, all of which provide key information to the lab in interpreting their instrument performance. More information on each report is available in the **IAMQC Peer brochure.**

Reagent Lot Report	Automates the tracking and reporting of reagent lot-to-lot variations between all peer groups.
Group Coordinator Report	A test-by-test listing of statistics of the laboratory and it's peer groups for up to 3 levels of control.
Levey-Jennings (LJ) Report	The LJ report displays individual QC values per analyte for the selected month. It also indicates when a reagent lot was changed.
Exceptions Report	This report details the lab's tests and analytical methods which differ in performance from its peer group using SDI and CVI.
Monthly Summary Report	A rolling twelve-month window of summary statistics, including monthly mean for each test and level is displayed along with peer group values.
Youden Plot	The Youden plot visualizes both bias and imprecision graphically and can be used to evaluate systematic and/or random error.
Six Sigma	The six sigma report automatically calculates the labs' sigma score by instrument and by assay, based on the Total Allowable Error values entered.
Measurement of Uncertainty (MoU)	The system calculates the MoU value automatically based on the time range selected for the lot in question along with the Standard Error of the Mean (SEM) value or the running SD of each test for the time period selected.
Bias Report	The Bias report contains all the information in the Group Coordinator report plus a bias score against the cumulative peer mean for each test and is generated in Microsoft excel format.



Support Services and Training

For support on generating automated reports in IAMQC® QC data management software, please contact **qcsoftware@technopathcd.com.**

Technopath Clinical Diagnostics provides a full suite of Quality Control training services supported by our training materials. For more information visit our **Knowledge Centre** where you can access our technical libraries for our QC materials and IAMQC® Data Management software tutorials and detailed user guides.

To learn more about Technopath Clinical Diagnostics and our customer value, please visit the "**Why Technopath"** section of our website, **www.technopathcd.com**.

References

[1] Algeciras-Schimnich, Alicia, PhD. "Tackling Reagent Lot-to-Lot Verification in the Clinical Laboratory." Clinical Laboratory News July 1 (2014): n. pag. Web. 15 May 2017.

[2] EP26-A: User Evaluation of Between-Reagent Lot Variation; Approved Guideline. Clinical and Laboratory Standards Institute. September 2013

[3] "Lot-to-Lot Variation" Simon Thompson, Douglas Chesher, Clin Biochem Rev. 2018 May; 39(2): 51–60. PMCID: PMC6223607

[4] Tricot, Mark X., PhD. "Q and A." CAP TODAY. College of American Pathologists, Dec. 2007. Web. 15 May 2017.

[5] IVDR Chapter III: Identification and traceability of devices, registration of devices and of economic operators, summary of safety and clinical performance, european database on medical devices. Section 20.4.1 (V).

[6] CAP All Common Checklist COM.30450

[7] Independent Quality Control and its importance. Are you dependent? Translated from Trillium Diagnostik 2019; 17(4): 157: In-vitro-Diagnostik, "Unabhängige Qualitätskontrolle und ihre Bedeutung: Sind Sie etwa abhängig?", Oswald Sonntag.

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