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Quality Assurance Training

Erythrocyte Sedimentation Rate

TRAINING AGENDA OVERVIEW

1

SEDiTROL® ESR Controls
– Control materials from ALCOR® Scientific

2

iQAP
– ALCOR® Scientific's peer-to-peer online quality assurance program

3

Proficiency Testing Overview

QUALITY ASSURANCE MANAGEMENT OVERVIEW

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Quality assurance (QA) in the laboratory is a critical function that ensures the accuracy, reliability, and integrity of laboratory testing processes and results.

External controls are used for routine monitoring and verification within the laboratory, whereas…

Proficiency testing provides an external assessment of laboratory performance against other laboratories in the field.

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QUALITY CONTROL TESTING

SEDiTROL ESR controls

WHY USE EXTERNAL CONTROLS

The use of quality control material is indicated as an objective assessment of the precision of methods and techniques in use and is an integral part of good laboratory practices.

- Since ESR is a physiological reaction, the use of external controls has more limitations than other methods.
- The guideline setting organizations realize the issue with using common controls across different ESR methods; it is impossible because different methodologies measure different parts of the erythrocyte sedimentation process.
- Therefore, ALCOR Scientific's SEDiTROL controls should be the only controls used with iSED® analyzers.

Because the phenomenon of ESR is confined to fresh blood and is transient, presently, the only feasible way of providing a control material is for the manufacturer or test developer to specify a method for the production of such material in the laboratory where it will be used. Due to the nature of the human erythrocyte sedimentation reaction, reference or control materials of the usual type are not available for the ESR test.

– CLSI Approved Standard 5th edition

CLSI. Procedures for the Erythrocyte Sedimentation Rate Test; Approved Standard— Fifth Edition. CLSI document H02-A5. Wayne, PA: Clinical and Laboratory Standards Institute; 2011.

SEDiTROL CONTROLS

- ALCOR Scientific provides SEDiTROL controls which are bi-level, human red cell-based contrived controls.
- SEDiTROL controls are barcoded so that the analyzers know they are controls.
- Using non-SEDiTROL controls is NOT recommended since iSED analyzers measure red blood cell aggregation and other control material may not aggregate.
- There is no contrived material that behaves exactly like human blood.
- Unknown control material is unable to be run on the analyzer since the aggregation kinetics for non-SEDiTROL material is unknown.

SEDiTROL QC STORAGE & STABILITY

- Do not refrigerate, freeze, or expose controls to excessive heat
- Stored at room temperature only (18°C to 30°C)
- Avoid prolonged exposure to light
- 18-month shelf life from the date of manufacture
- 60-day open vial stability
- Store upright
- Mix well* before analysis

***It is important to follow the SEDiTROL Instructions for Use for proper mixing and storage of QC material.**

Hand mixing is NOT a supported practice with SEDiTROL controls.

QC RECOMMENDATIONS

- ALCOR Scientific recommends running SEDiTROL quality controls at least once per day, however, it is up to each individual lab to determine the quantity and frequency of controls they run.
- Each new set of SEDiTROL controls must be placed on a rocker for 25 minutes prior to first use then mixed for five minutes each day of use until depleted or expired. For iSED PRO this is performed automaticaally within the software.
- An additional 20 µL of sample is withdrawn from the first test run following a wash cycle. To ensure the volumes for SEDiTROL Level 1 and Level 2 remain as consistent as possible it is recommended to alternate the order controls are run each day. We suggest to start with Level 1 controls on all odd days and Level 2 on all even days in the month.
- Enrol in ALCOR Scientific's iQAP Quality Assurance Program for unlimited online access to Levy Jennings reports and to see how your laboratory's QC results compare to the peer group.

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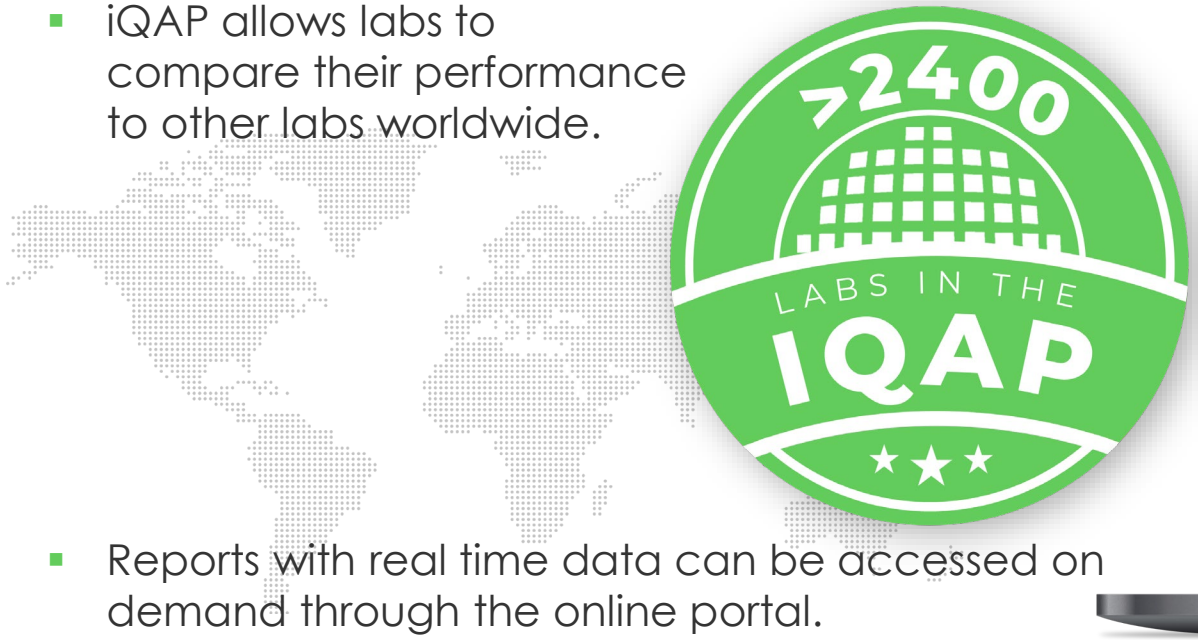
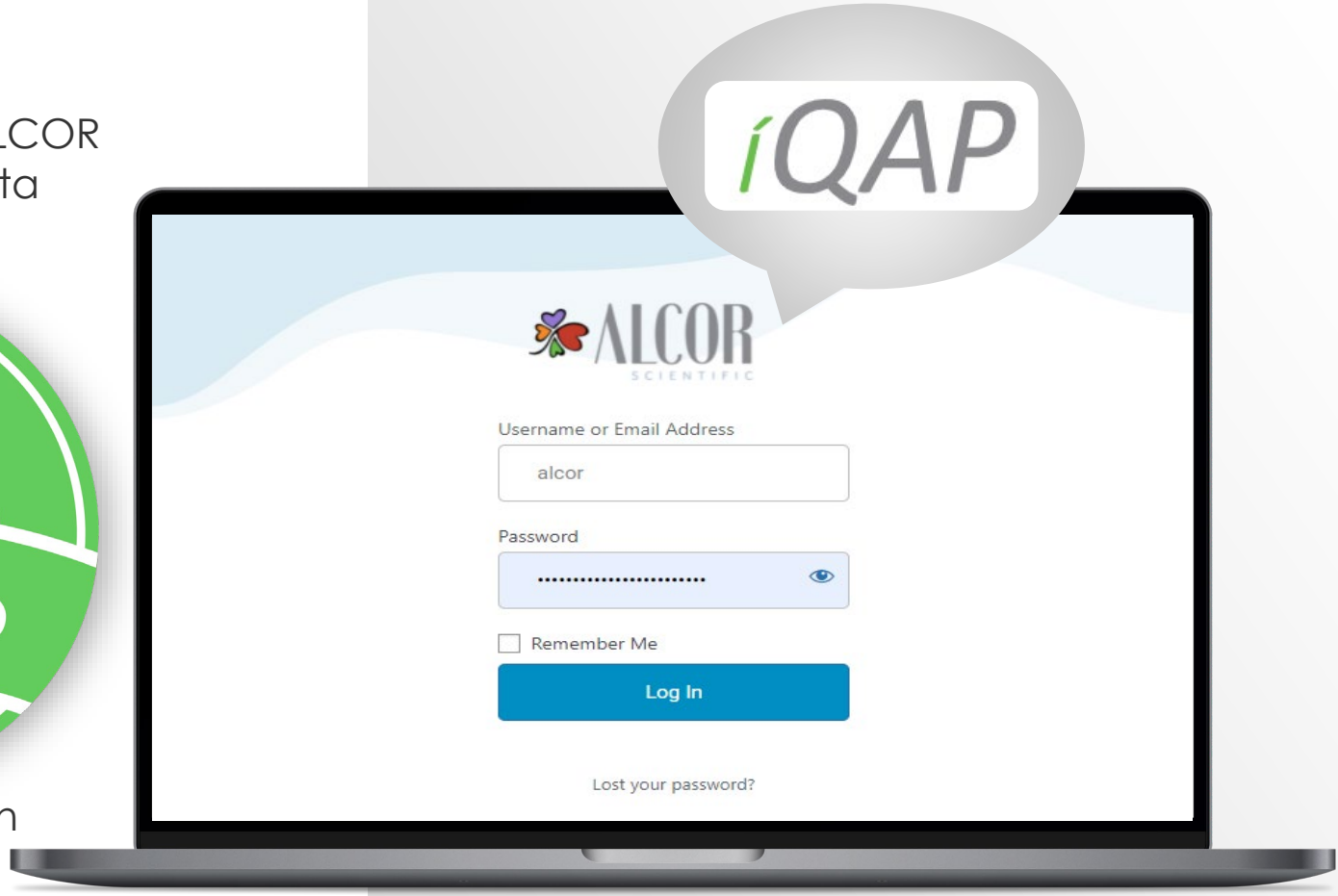
iQAP USER GUIDE

Using the online Quality Assurance Program

PEER-TO-PEER QUALITY ASSURANCE PROGRAM

- All SEDiTROL customers have access to iQAP, ALCOR Scientific's convenient online quality control data management program.
- iQAP allows labs to compare their performance to other labs worldwide.



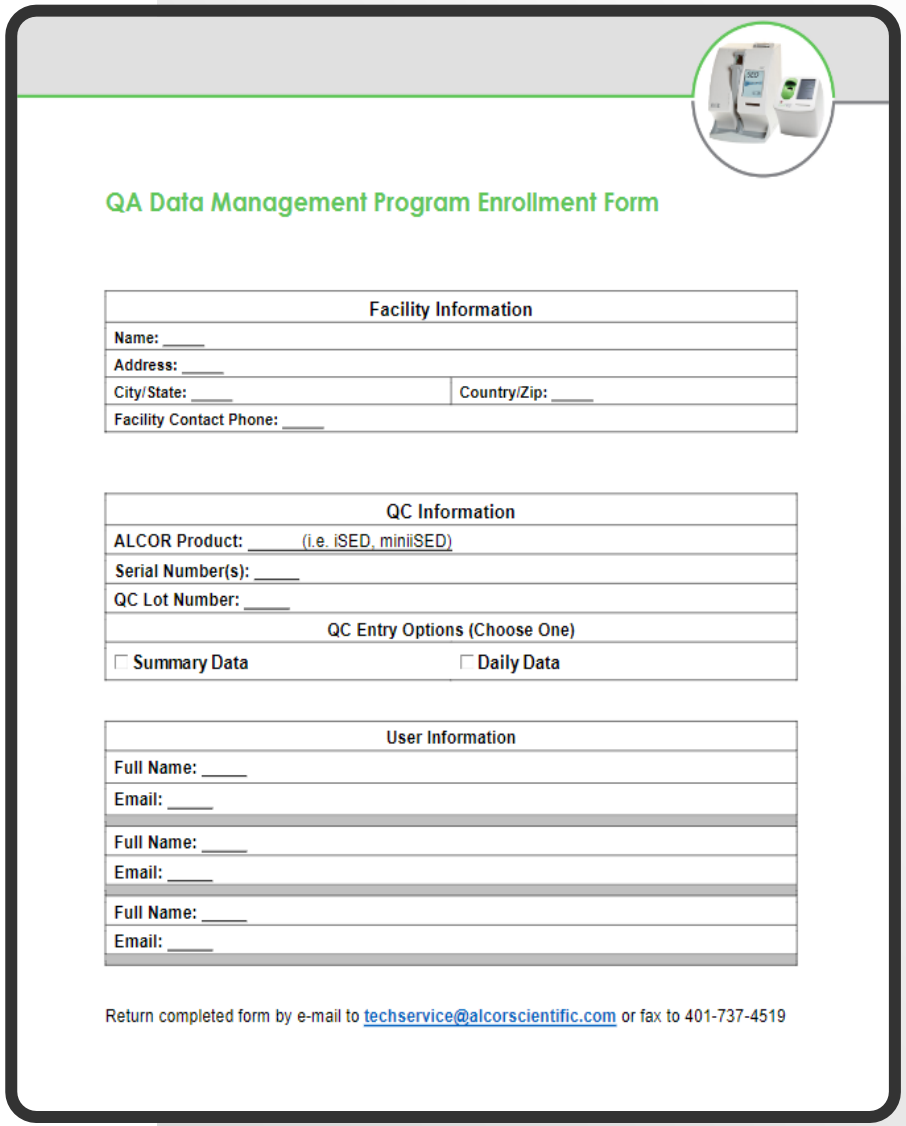


- Reports with real time data can be accessed on demand through the online portal.
- Access is managed by ALCOR Scientific Technical Support.

iQAP ENROLLMENT

To participate in this program, please complete the registration form which is downloadable from the ALCOR Scientific website.

Requests and completed registration forms should be sent to techservice@alcorscientific.com.



QA Data Management Program Enrollment Form

Facility Information	
Name: ____	
Address: ____	
City/State: ____	Country/Zip: ____
Facility Contact Phone: ____	

QC Information	
ALCOR Product: ____(i.e. iSED, miniiSED)	
Serial Number(s): ____	
QC Lot Number: ____	
QC Entry Options (Choose One)	
☐ Summary Data	☐ Daily Data

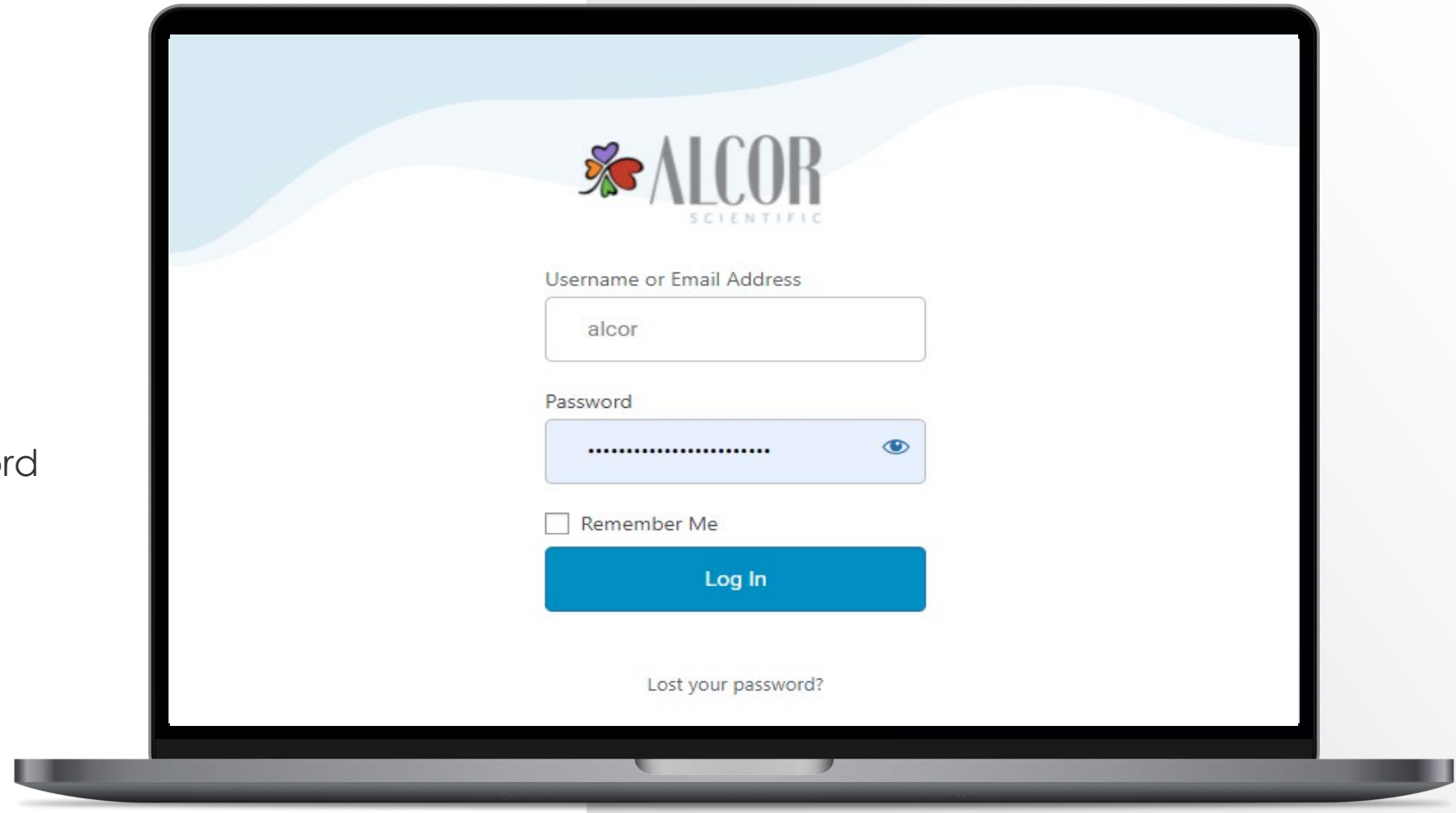
User Information
Full Name: ____
Email: ____
Full Name: ____
Email: ____
Full Name: ____
Email: ____

Return completed form by e-mail to techservice@alcorscientific.com or fax to 401-737-4519

LOGIN TO iQAP

Once enrolled...

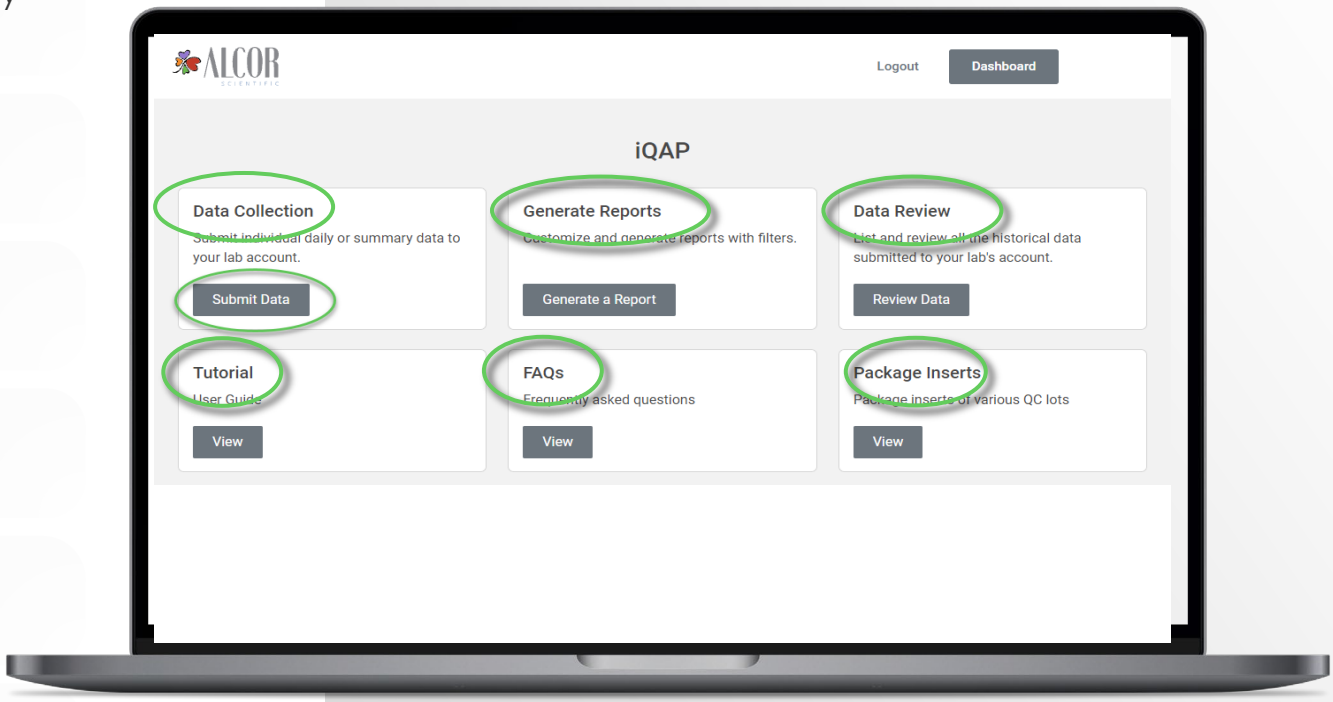
- Go to the website www.https://iqaponline.com
- Enter your username and password
- Click 'Login'



HOME PAGE LAYOUT

From the Home Page you can easily navigate to various functions you will need to record, monitor and report your quality control results.

- **Data Collection** is used to submit your individual daily or summary data to your account.
- **Generate Reports** allows you to customize and generate reports with filters and peer data.
- **Data Review** provides a list and allows you to review historical data you have submitted to your account.
- **Tutorial** is the User Guide to help you navigate the website.
- **FAQs** provides answers to Frequently Asked Questions.
- **Package Inserts** allows you to view the lot specific Instructions for Use.



DATA COLLECTION - SUMMARY DATA

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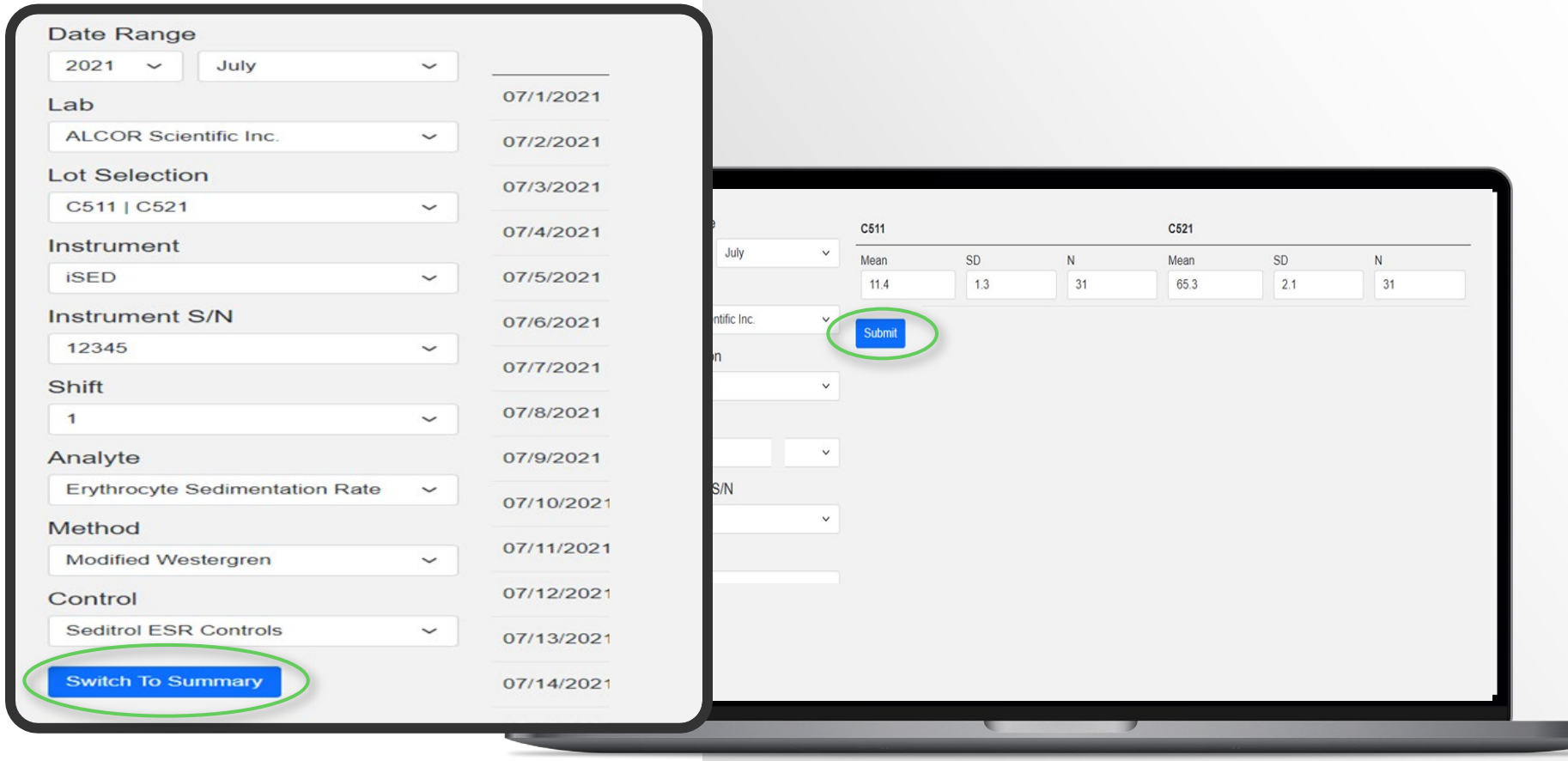
1. Clicking "Submit Data" will bring you to the Enter Data Results page.
2. Use the dropdowns on the left side of the screen to select your data.
3. Click on the 'Switch to Summary' button to input your data.
4. Enter the Mean, SD and N (number of points) for SEDiTROL Level 1 and Level 2.
5. Click 'Submit.



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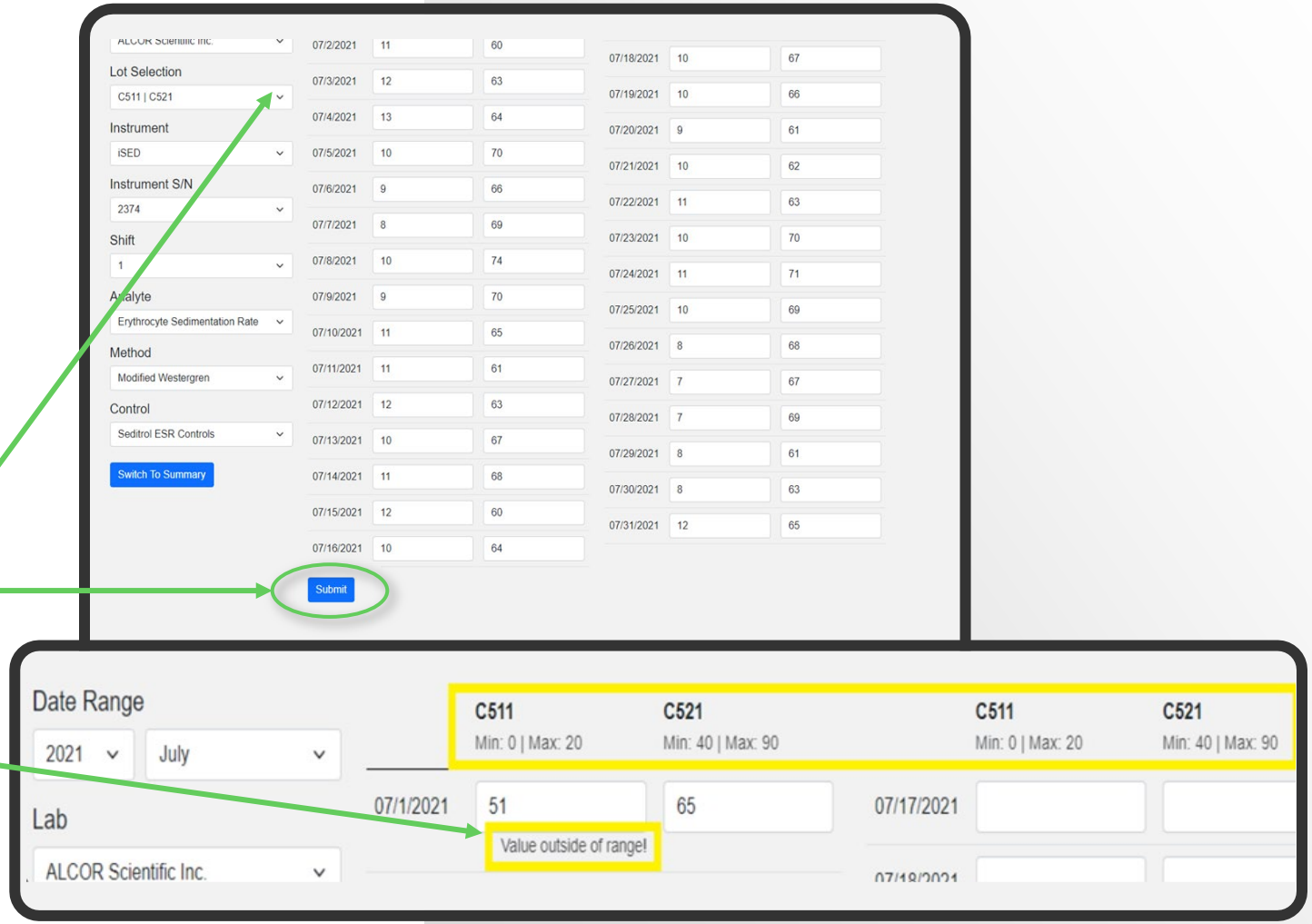
DATA COLLECTION INDIVDUAL DAILY DATA

You may enter your QC data on a daily basis, or the entire month may be entered at one time.

From the Home Page, select the 'Submit Data' button. You will be brought to the Enter Data Results page

Note: Please ensure that you enter your data by the 5th of each month to capture the full month date range and daily data points in your reports.

1. Use the dropdowns on the left side of the screen to select your data.
2. Enter the individual values and click 'Submit'.
3. If the data is out of acceptable range, it will be flagged when entered.



Follow your laboratory protocol to address results that are flagged

REPORTS

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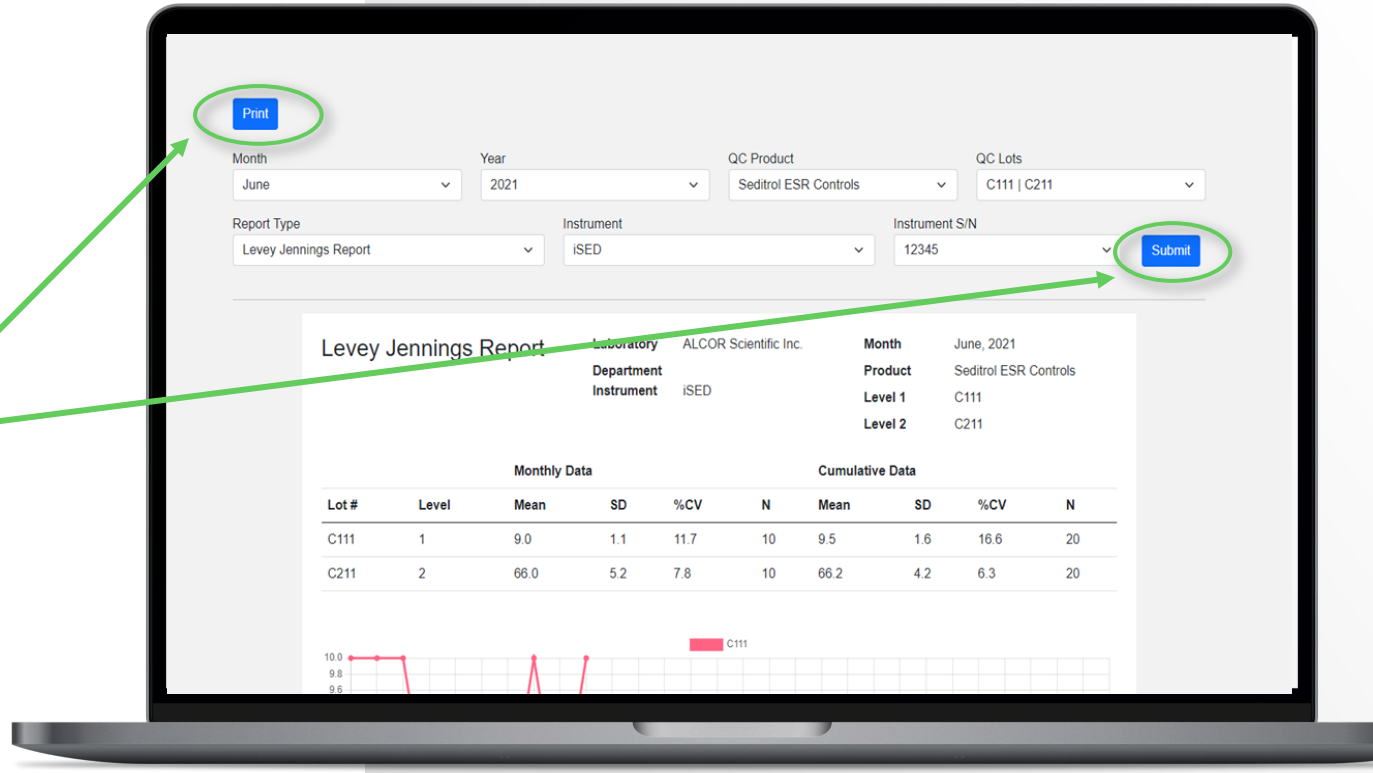
1. On the Home Page select the 'Generate Reports' tile.
2. Use the dropdown menu to choose the correct information and report type you wish to generate.
3. Use the 'Submit' button to generate the selected report and the 'Print' button to generate a hard copy.
4. If the data is out of acceptable range, it will be flagged when entered.



Reports available:

- Levey Jennings
- Group Coordinator
- Exceptions
- Summary

All reports are accessible if submitting summary data

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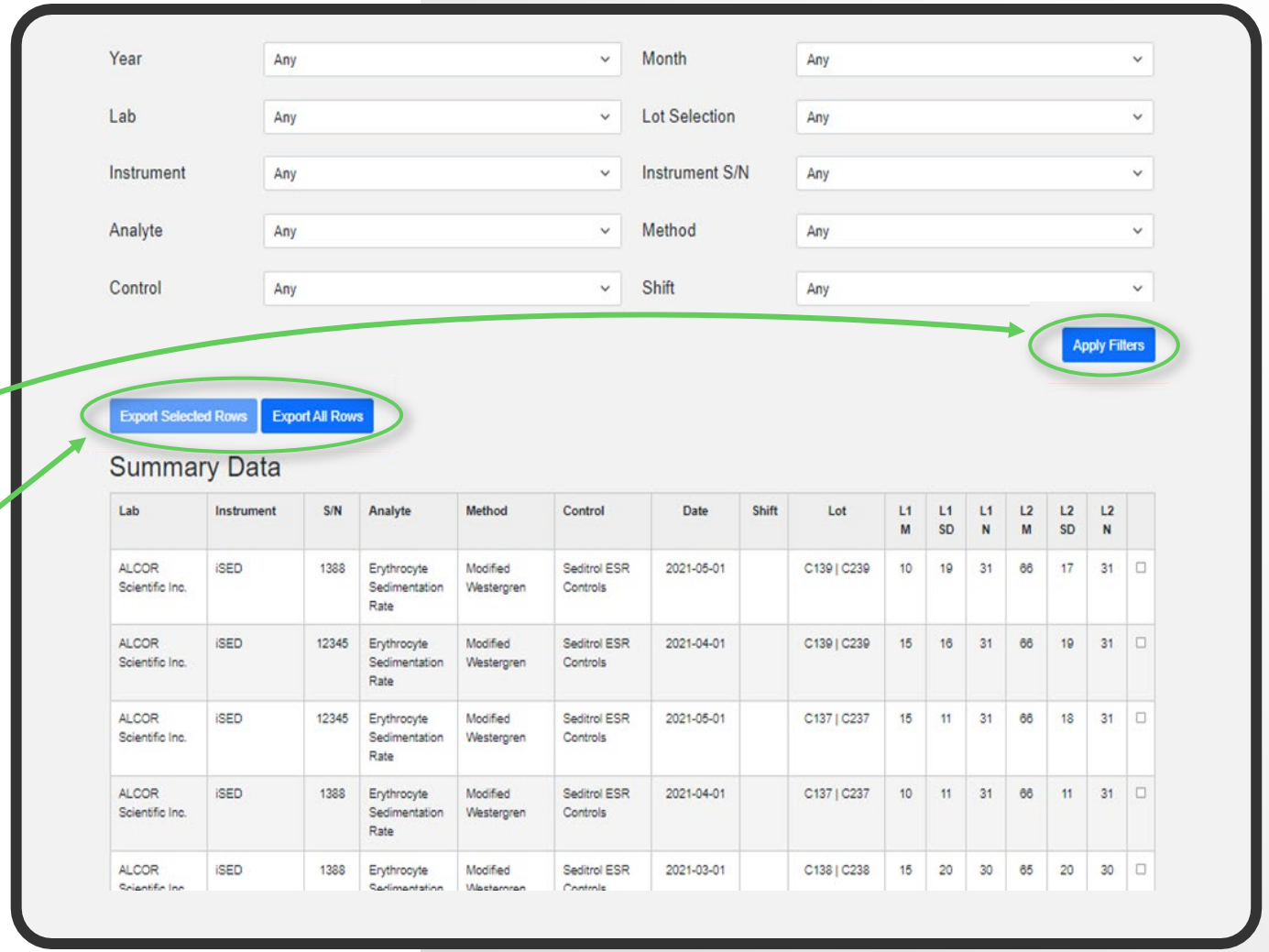
DATA REVIEW

1. From the Home Page, select the 'Data Review' tile.
2. Use the available dropdown menus to filter which information you want to be displayed.
3. Click the 'Apply Filters' button to display the information.
4. Click 'Export Selected Rows' or 'Export All Rows' to download or print the data.



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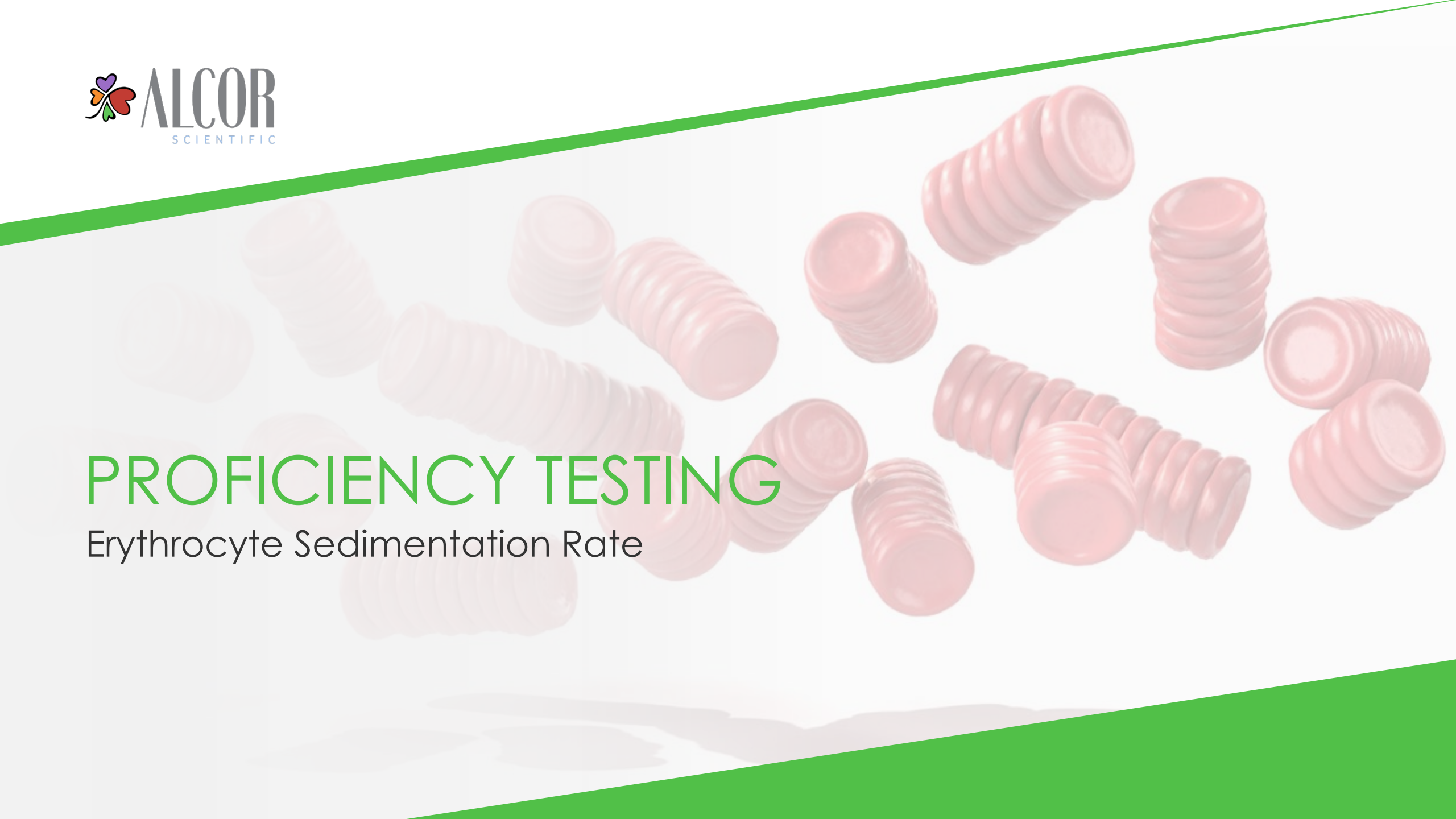


PROFICIENCY TESTING

Erythrocyte Sedimentation Rate

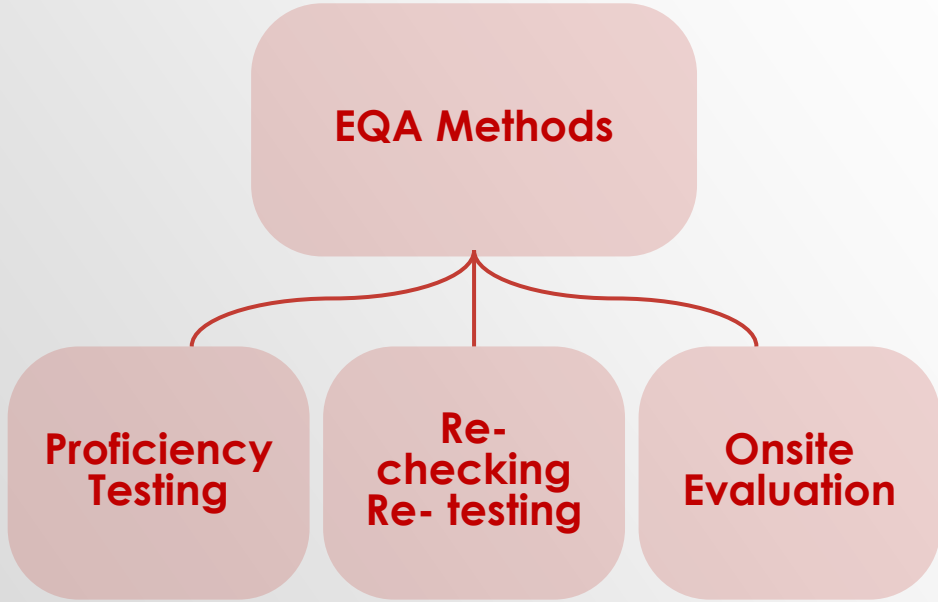
WHAT IS EXTERNAL QUALITY ASSESSMENT?

Quality assessment is a crucial component of laboratory quality management and can be executed through various methods.

EQA involves comparing a laboratory's testing performance to an external source, such as:

- **Peer laboratories (e.g. iQAP program)**
- **A reference laboratory**

EQA serves as an objective system for evaluating a laboratory's performance using an external agency or facility.



WHAT IS PROFICIENCY TESTING?

Proficiency testing (PT), is a widely adopted form of external quality assessment (EQA). It serves as a robust method, capable of assessing various laboratory techniques.

- ALCOR Scientific typically works with proficiency providers to assay the material and provide lot-specific barcodes prior to sample distribution to end users.
- In the US, the College of American Pathologists (CAP) offers a survey specifically designed for iSED in addition to the general ESR survey.

ISO/IEC Guide 43-1:1997: "Proficiency testing schemes (PTS) are interlaboratory comparisons that are organized regularly to assess the performance of analytical laboratories and the competence of the analytical personnel".

CLSI: "A program in which multiple samples are periodically sent to members of a group of laboratories for analysis and/or identification; whereby each laboratory's results are compared with those of other laboratories in the group and/or with an assigned value and reported to the participating laboratories and others".

1. Jou JM, Lewis SM, Briggs C, Lee SH, De La Salle B, McFadden S; International Council for Standardization in Haematology. ICSH review of the measurement of the erythocyte sedimentation rate. Int J Lab Hematol. 2011 Apr;33(2):125-32. doi: 10.1111/j.1751-553X.2011.01302.x. Epub 2011 Feb 25. PMID: 21352508.
2. CLSI. Procedures for the Erythrocyte Sedimentation Rate Test; Approved Standard— Fifth Edition. CLSI document H02-A5. Wayne, PA: Clinical and Laboratory Standards Institute; 2011.

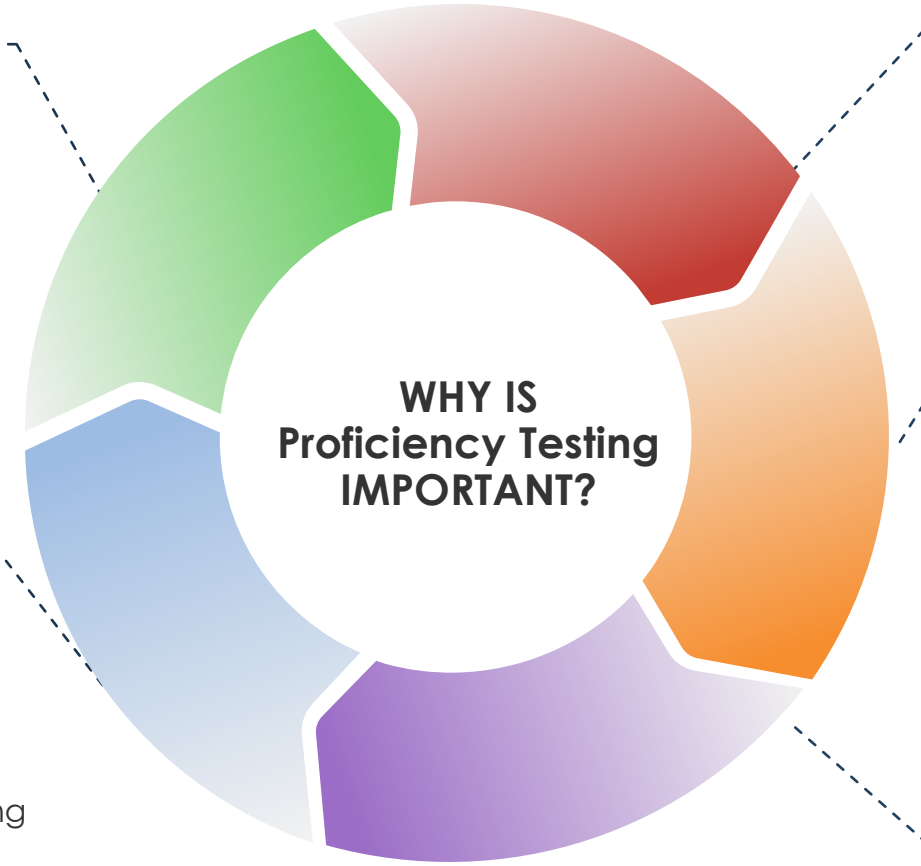
WHY IS PROFICIENCY TESTING IMPORTANT?

External Validation

PT provides external validation of laboratory testing methods by comparing results with those of other laboratories. This external perspective helps identify areas for improvement and promotes transparency and credibility in laboratory practices.

Quality Assurance

PT helps ensure the accuracy and reliability of laboratory test results by comparing them to known standards or consensus values. It identifies any discrepancies or systematic errors in testing procedures, allowing laboratories to take corrective actions to improve quality.



Regulatory Compliance

Many regulatory bodies, such as the Clinical Laboratory Improvement Amendments (CLIA) in the United States, require laboratories to participate in PT programs to maintain accreditation and ensure compliance with quality standards.

Continuous Improvement

Participation in PT encourages laboratories to continuously monitor and improve their testing processes. By regularly benchmarking their performance against others, laboratories can identify best practices and implement quality improvements.

Enhanced Patient Care

Accurate and reliable laboratory test results are essential for making informed clinical decisions and providing optimal patient care. PT helps ensure that laboratories produce reliable results, contributing to better patient outcomes

PROFICIENCY PROVIDERS

	PROGRAM	SURVEY CODE	SURVEY FREQUENCY	CHALLENGES	REGION	WEBSITE
COLLEGE of AMERICAN PATHOLOGISTS	**College of American Pathologists(CAP)**	ESR3	2 surveys per year	3	International	www.cap.org
American Proficiency Institute	**American Proficiency Institute(API)**	Sedimentation Rate- D	3 surveys per year	2	International	www.api-pt.com
Wisconsin State Laboratory of Hygiene UNIVERSITY OF WISCONSIN-MADISON	**Wisconsin State Laboratory of Hygiene(WSLH)**	PT02520 Sedimentation Rate – iSED (SRI)	2 surveys per year	3	US only	www.slh.wisc.edu
ESfEQA European Society for External Quality Assessment	**European Society for External Quality Assessment (ESfEQA)**	ESRAL	2 surveys per year	2	Europe	www.esfeqa.eu
UK NEQAS Haematology	**NEQAS**	ESR	4 surveys per year	2	International	www.ukneqas.org

THANK YOU!

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