Answering your questions

Overheated cryoglobulin sample

Q The beginning of our procedure for testing a blood sample for cryoglobulins calls for heating the drawtube at 37°C for at least one hour. If the sample is left in the 37°C water bath overnight, is it still good to test? I could not find anything in our textbooks that states otherwise, and the procedure does state “... at least one hour.”

A In your question, you did not tell us whether it was the whole-blood sample or separate-serum sample that was left in the 37°C water bath overnight. If a properly collected blood is obtained, however, and the serum is separated at 37°C, then leaving the serum sample in a 37°C water overnight probably should not interfere with the laboratory testing for cryoglobulins.

There are three types of cryoglobulins, which differ in their composition. The different types can contain monoclonal and polyclonal immunoglobulins, IgM rheumatoid factors, and complement components.1,2

Importance of proper specimen collection

In the testing for cryoglobulins, the collection of serum for testing is very important. Common errors include: a) loss of cryoglobulins due to failure to properly separate serum from whole blood; b) loss of cryoprecipitate due to cooling before centrifugation; and c) inadequate volume of serum for testing of cryoglobulins present at low levels.

Kallemuchikkal and Gorevic3 recommend that 10 mL to 20 mL of blood be collected in a tube or syringe prewarmed to 37°C and the sample be allowed to clot at 37°C for at least 30 minutes prior to separation. The cryoglobulin levels may vary from 50 µg/mL to 100 µg/mL to 5 mg/mL to 10 mg/mL or higher.

Tips from the clinical experts

Edited by Daniel M. Baer, MD

Tips from the clinical experts provides practical, up-to-date solutions to readers’ technical and clinical issues from a panel of experts in various fields. Readers may send questions to Dan Baer by e-mail at tips@mlo-online.com.
If a test procedure has neither calibration nor control materials, the lab needs to establish procedures to verify the reliability of patient test results. This needs to include methods for verifying accuracy and precision as well as verifying reliability at clinical-decision points. This is stated in the CAP Laboratory general checklist, item GEN.30070.

The instrument manufacturer’s procedures suggest a method for accuracy verification by comparing blood-test results from the instrument with a co-oximeter. The co-oximeter is used as the reference analyzer and the POCT instrument must be within 3% of the %SO₂M of the co-oximeter. The manufacturer further suggests a frequency for this comparison of every 30 to 90 days.

The filters used as daily controls are acceptable if the following criteria are met:

1. The system is FDA-cleared or approved.
2. The system is classified as waived or moderately complex under CLIA 88.
3. The POCT program has performed and documented studies to validate the adequacy of limiting daily QC to the internal controls.
4. External controls are run for each new lot number or shipment of test materials (or at the frequency defined by the manufacturer if more often than each lot).

Frequency for QC for co-OX is at least every 24 hours; however, there is a requirement for QC every eight hours for blood gases pO₂, pCO₂, and pH.

Proficiency testing would serve as another means of verifying accuracy, but it would not be required if %O₂ saturation is also tested on another instrument under the same CLIA number, and proficiency testing is performed and reported on that instrument. It is required, however, that the POCT O₂-saturation instrument then be tested against that instrument performing the %O₂ saturation for comparability of patient results at least every six months.

—Mindy Aichele, MT (ASCP), CLS(NCA)
Point-of-Care Coordinator
Oregon Health Sciences University
Portland, OR; and
Barbara Cebulski, MT(ASCP)
Inspection Specialist, CAP LAP
Northfield, IL

Pediatric reference ranges derived by different methodologies

Q We are a mid-size hospital with low pediatric volume due to a nearby children’s hospital. Can I use a reference range from literature if I do not have access to pediatric specimens to establish my own? I am nervous about using a reference range based on another methodology.

A Identifying pediatric reference intervals is a continuing problem for all laboratories. Numerous factors need to be considered including age, sex, diet, drugs, posture, stress, and time of day. The process of transferring and validating appropriate reference ranges or reference intervals, however, is the same for both adult and pediatric patients. This process has been spelled out in the document “How to Define and Determine Reference Intervals in the Clinical Library” available from the Clinical Laboratory Standards Institute (CLSI; formerly NCCLS) in Wayne, PA.

It is acceptable to use a manufacturer’s reference interval or a reference interval from another lab using a similar analytical system. If the method is markedly different, this process cannot be used. This process, called transference, needs to be assessed for acceptability (validation). Three validation processes are delineated in the CLSI reference; I will only describe two in general terms. Please see the reference for further details.

The first validation process is a subjective assessment. The laboratory must determine that the population tested for the transferred reference interval is similar to your testing population. Next, the pre-analytical and analytical procedures must be reviewed to determine if they are consistent with the processes in your laboratory.

In the second validation process, 20 specimens that represent your sampling population are identified and tested. The 95% reference interval is validated if no more than two of 20 test values exceed the proposed interval. If three or more values are identified, then the process should be repeated with an additional 20 specimens and checked for outliers.

If there are three or more outliers on the second set, then further investigation into the analytical process and reference populations need to be initiated. If there is no explanation for the observed differences, then the laboratory may need to develop its own reference interval.

—Stanley F. Lo, PhD
Technical Director
Clinical Chemistry
Children’s Hospital of Wisconsin
Milwaukee, WI

Reference

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