

IQVIA Laboratories “How To” Guide

*How To Prevent Cancelled tests (including
Additional Test Information)*

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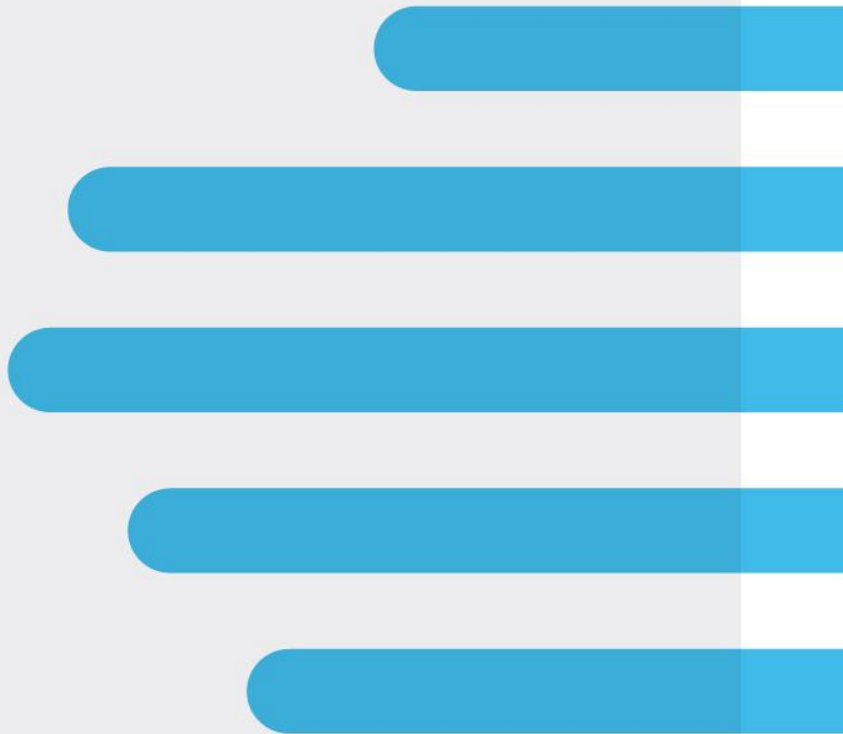


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IQVIA LABORATORIES TEST CANCELLATIONS

IQVIA Laboratories will automatically cancel a test under each of the circumstances outlined below. This information will be noted on the Laboratory Report.

1. The specimen is received past the established limits of stability for the requested tests.
2. The hematology tube is clotted.
3. Platelet clumping occurs.
4. The specimen is not processed as per instructions in the laboratory manual.
5. Incomplete or illegible requisition when follow-up phone calls fail to resolve the query.
6. The specimen's integrity is in question. This could include but, is not limited to:
 - Results incompatible with life.
 - Results not conforming to expected algorithmic patterns.
7. The specimen is contaminated. This could include but is not limited to:
 - Contamination with interstitial fluid (coagulation studies)
 - Contamination with bacteria
 - Contamination with red blood cells
 - Contamination with I.V. fluid
8. Specimen is grossly haemolysed.
9. Specimen is grossly lipemic or icteric.
10. Collection date and/or time is confirmed to be beyond established stability.
11. Specimen quantity is not sufficient (QNS) or empty tube is received.
12. The specimen does not have 2 identifiers to link the specimen back to the requisition form of the patient.

CANCELLATION COMMENTS

The below table provides additional information on the most commonly encountered cancellation comments that you may see from IQVIA Laboratories and possible ways to avoid cancelled tests.

Cancellation Comment	Possible Cause	How to prevent future cancellations
No Sample Received	No sample or wrong sample received by the lab.	<p>Follow instructions in laboratory manual and on requisition forms carefully.</p> <p>Collect all required samples for visit.</p> <p>It may be that the investigator never intended for this testing to be done. This needs to be clear on the requisition form.</p>
Quantity Not Sufficient - <i>Insufficient sample to perform testing</i>	<p>Blood draw tubes not filled.</p> <p>Serum/plasma not dispensed accurately into multiple tubes.</p>	<p>Follow sampling instructions carefully.</p> <p>For EDTA tubes, fill contents to the mark. This is important as insufficient blood with the fixed amount of coagulant in the tube will affect the sample quality.</p> <p>Ensure the tubes are capped tightly to avoid leaking during transport.</p>
Unable To Obtain Valid Results	<p>Unknown interference with one or more analytical tests:</p> <ul style="list-style-type: none">• drugs ?• IV fluids?• wrong tube? EDTA?	<p>Wherever possible samples should be taken from a venipuncture.</p> <p><u>Be careful if using a cannula.</u></p> <p>Ensure that samples are properly centrifuged.</p>

Cancellation Comment	Possible Cause	How to prevent future cancellations
Haemolysis - <i>Leakage of haemoglobin from red blood cells</i>	Difficult blood draw.	Always draw directly into EDTA tube.
	Rough handling, e.g., vigorous mixing.	Mix promptly by gentle inversion. <u>Do not mix vigorously.</u>
	Samples taken by syringe and squirted into EDTA tube.	Minimise the use of syringes for blood collection. If you do use a syringe, inject the blood gently into the draw tube.
	Sample has frozen and thawed.	Follow packaging instructions carefully.
Sample Not Centrifuged Or Inadequately Centrifuged At Site	Sample has been centrifuged too slowly, for too short a time, or not at all. This applies to gel tubes where the draw tube should be centrifuged and sent to IQVIA Laboratories without transferring the serum to a secondary tube.	Spin gel tubes for the recommended time, allowing time for the centrifuge to get up to speed. The gel barrier in the tube needs time to move and form a solid barrier between the red cells and the serum. If the gel has not moved to the middle of the tube, it must be centrifuged again, faster, or for longer. Make sure the centrifugation speed is adequate. The gel will move at speeds well below what we recommend. This may be enough to sediment the red cells but not enough to make the gel form a barrier between the red cells and the serum.

Cancellation Comment	Possible Cause	How to prevent future cancellations
<p>Sample Clotted - <i>EDTA Sample Has Clotted</i></p> <p>Fibrin Clots - <i>Microclots that result from partial coagulation of the blood</i></p>	<p>Sample starting to clot before anti-coagulant is mixed, i.e., sample laid aside before being mixed with the anti-coagulant.</p> <p>Difficult venipuncture.</p>	<ul style="list-style-type: none"> • Always draw directly into EDTA tube. • Mix the EDTA tube promptly by gentle inversion. • If syringe is used, arrange to transfer the blood to vacutainer and mix promptly. • <u>Do not store samples in the refrigerator.</u> Samples should be maintained at approximately 25 degrees Celsius. • Ensure the EDTA sample is fully covered in the gel wrap. The gel protects the sample from freezing in very low ambient temperatures. • Ensure tubes are warmed before blood draw. Example: Use both hands/palms to warm the tubes. • Good venipuncture technique.
Platelet Clumping **	Same causes as clotting.	The blood of some patients is predisposed towards platelet clumping in EDTA tubes. In these patients, it may be best to collect the blood into a sodium citrate tube as well as the EDTA tube; please speak with your IQVIA Laboratories Project Manager regarding this.

** Platelets have a tendency to clump and, whilst the EDTA in the haematology tube should prevent this, sometimes it is not completely successful. When platelets clump, it is impossible to count them accurately. If we do not see a shortage of platelets, a comment will be added to the laboratory report indicating them as “adequate”.

Platelet clumps may incorporate white blood cells, making it impossible to count these accurately either.

Cancellation Comment	Possible Cause	How to prevent future cancellations
Degenerated Cells	<p>White blood cells deteriorating in the collection tube more rapidly than normal.</p> <p>High ambient temperatures will contribute to this.</p>	<p>White blood cells in some individuals are prone to rapid degeneration.</p> <p>Aim for the shortest possible delivery time. Ship samples as per the flowchart and requisition forms and adhere to last call by times provided by courier.</p> <p>Follow packaging instructions carefully.</p>
Specimen collection materials beyond expiry date	<p>An expired tube has been used to collect and/or transfer the specimen.</p> <p>NOTE: A query will be sent by IQVIA Laboratories upon receipt of any expired kit. Investigator sites are required to respond to query to confirm if expired tubes were replaced with non-expired tubes prior to sample collection. If expired tubes were not replaced, impacted tests will be cancelled.</p>	<p>Check expiration date on the label of the kit packaging. This shows the earliest expiration date of all tubes within the kit. Expiry date of individual tubes should be visible on the manufacturers label, where applicable.</p> <p>Expired lab kits can still be used, providing any expired tubes are replaced with non-expired tubes. Ensure any replacement tubes are labelled using the Z-labels within the lab kit and provide the expiry date in the requisition form or via query so IQVIA Laboratories can resolve them and result every tests.</p> <p>IMPORTANT: Ensure a response to the associated query is provided as soon as possible.</p>

FURTHER INFORMATION - CANCELLED TESTS

Any cancelled tests will also be indicated on the laboratory reports provided for the associated visit. If any additional information is required, please contact IQVIA Laboratories. Cancellations will occur in all instances where reliable analysis and resulting is not possible, and the appropriate cancellation comment would be included on the lab report.

REPEAT ANALYSIS

IQVIA Laboratories will provide repeat analysis on specimens previously received at the central laboratory, provided the elapsed time does not exceed the established stability limits. The investigator should call IQVIA Laboratories to request repeat analysis

NOTE: IQVIA Laboratories are unable to advise whether or not a test should be repeated following cancellation. Please contact the medical monitor for your study to determine whether a retest is required or not.

ADDITIONAL TEST INFORMATION - BIOTIN TEST INTERFERENCE

Dietary supplements containing large doses of biotin may interfere with some laboratory immunoassays and may skew results to be either falsely high or falsely low. For patients receiving the recommended daily doses of biotin supplements, results may potentially be skewed if samples are collected in less than 8 hours following the last biotin supplementation. For patients on massive doses greater than 5 milligrams/day of biotin supplements, results may potentially be skewed if samples are collected in less than 3 days following the last biotin supplementation. For patients on mega doses greater than 100 milligrams/day of biotin supplements, results may potentially be skewed if samples are collected in less than 6 days following the last biotin supplementation.

REVISION LOG

Date/Version	Page(s)	Revision	Notes
V01 August 2025	N/A	N/A – first version	