# **Q**<sup>2</sup> Solutions<sup>®</sup>



**Q**<sup>2</sup> Solutions How Do I...? Guides for Site Coordinators

# How Do I Prevent Cancelled Tests?

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#### **Q**<sup>2</sup> Solutions Test Cancellations

Q<sup>2</sup> Solutions 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.
- 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.



## **Q**<sup>2</sup> Solutions Test Cancellations (continued)

- 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).
- 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 Q<sup>2</sup> Solutions 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.	Follow instructions in laboratory manual and on requisition forms carefully.
		Collect all required samples for visit.
		It may be that the investigator never intended for this testing to be done. This needs to be clear on the requisition form.
Quantity Not Sufficient -	Blood draw tubes not filled.	Follow sampling instructions carefully.
Insufficient sample to perform testing	Serum/plasma not dispensed accurately into multiple tubes.	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.
		Ensure the tubes are capped tightly to avoid leaking during transport.
Unable To Obtain Valid Results	Unknown interference with one or more analytical tests:	Wherever possible samples should be taken from a
	• drugs ?	venipuncture.
	• IV fluids?	Be careful if using a cannula.
	wrong tube? EDTA?	Ensure that samples are properly centrifuged.



# Cancellation Comments (continued)

<b>Cancellation Comment</b>	Possible Cause	How to prevent future cancellations
Haemolysis - Leakage of haemoglobin from red blood cells	Difficult blood draw.  Rough handling, e.g., vigorous mixing.  Samples taken by syringe and squirted into EDTA tube.  Sample has frozen and thawed.	Always draw directly into EDTA tube.  Mix promptly by gentle inversion. Do not mix vigorously.  Minimise the use of syringes for blood collection. If you do use a syringe, inject the blood gently into the draw tube.  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 Q² Solutions 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 Comments (continued)**

<b>Cancellation Comment</b>	Possible Cause	How to prevent future cancellations
Sample Clotted - EDTA Sample Has Clotted  Fibrin Clots - Microclots that result from partial coagulation of the blood	Sample starting to clot before anti-coagulant is mixed, i.e., sample laid aside before being mixed with the anti-coagulant.  Difficult venipuncture.	<ul> <li>Always draw directly into EDTA tube.</li> <li>Mix the EDTA tube promptly by gentle inversion.</li> <li>If syringe is used, arrange to transfer the blood to vacutainer and mix promptly.</li> <li>Do not store samples in the refrigerator. Samples should be maintained at approximately 25 degrees Celsius.</li> <li>Ensure the EDTA sample is fully covered in the gel wrap. The gel protects the sample from freezing in very low ambient temperatures.</li> <li>Ensure tubes are warmed before blood draw. Example: Use both hands/palms to warm the tubes.</li> <li>Good venipuncture technique.</li> </ul>
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 Q <sup>2</sup> Solutions Project Manager regarding this.

<sup>\*\*</sup> 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 Comments (continued)

Cancellation Comment	Possible Cause	How to prevent future cancellations
Degenerated Cells	White blood cells deteriorating in the collection tube more rapidly than normal.	White blood cells in some individuals are prone to rapid degeneration.
	High ambient temperatures will contribute to this.	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.
		Follow packaging instructions carefully.



#### **Cancelled Tests**

Any cancelled tests will also indicated on the laboratory reports provided for the associated visit. If any additional information is required, please contact Q<sup>2</sup> Solutions.

That 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

Q<sup>2</sup> Solutions 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 Q<sup>2</sup> Solutions to request repeat analysis.

NOTE: Q<sup>2</sup> Solutions 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.

#### **Pending Tests**

Q<sup>2</sup> Solutions will release lab reports with pending results only when the LTMS Study Database is configured for Partial Reporting for a specific report.

