Data Clarification Queries (DCQ) Guideline for Site Coordinators

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List of Common Abbreviations

AP	Anatomic Pathology
Accession#	Accession number
ADT question	Administrative question found on requisition form, applicable for the visit
CRA	Clinical Research Associates
DCQ	Data Clarification Queries
DOB	Date of Birth
LTMS	Laboratory Trial Management System
Req form	Requisition form
U/R	Unscheduled/Retest
ISS	Investigator Site Support

What are Data Clarification Queries (DCQs)?

Upon receipt of laboratory samples, IQVIA Laboratories performs a series of edit checks on the patient demographics and visit information. If all data is found to be consistent and correct, the results will be released to the site. However, on occasion, clarification of the data is required by the site to ensure the integrity of the data provided.

The following table provides examples of possible situations that can result in a query being generated to the investigator site.

Query	Example
Demographic Discrepancy	Demographic data provided for the current subject visit does not match the Demographic data provided at a previous subject visit.
Incorrect Shipping Conditions/the state in which the specimen was shipped does not the match the expected specimen state	Frozen samples received in an ambient condition.
Collection Date Matches Date of Birth	Specimen collection date provided matches the DOB provided for the current subject visit.
Duplicate Subject ID	Subject ID provided matches that of another subject in the system.

Importance of Responding to DCQs

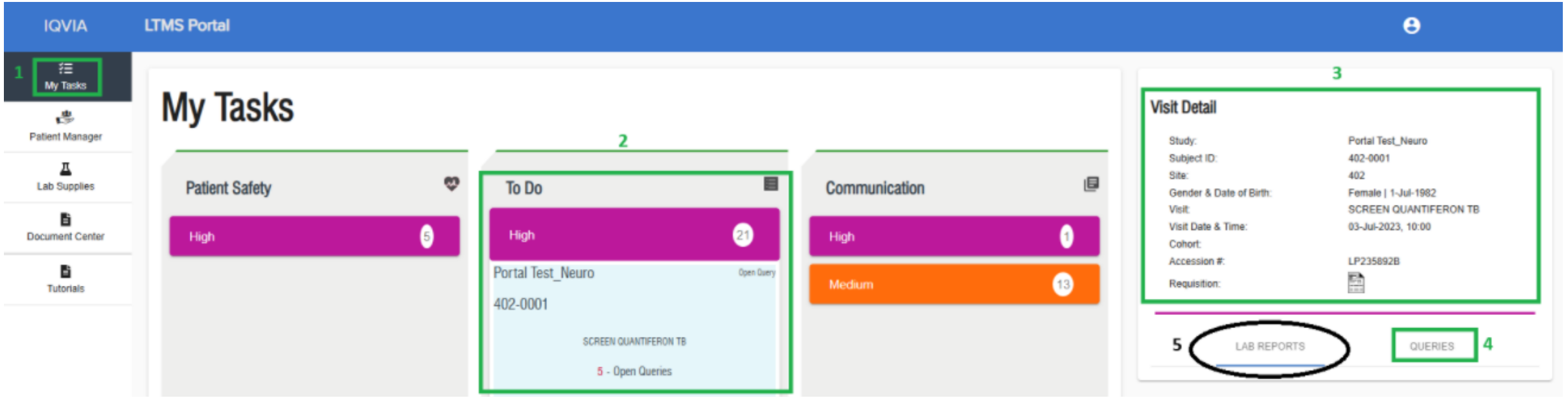
- Accession numbers which are remanded to a DCQ in the database have a **hold** applied on:
  - Lab report release (including safety reports)
  - Shipment of specimen management samples to other labs

- It’s therefore very important that DCQs are resolved as quickly as possible, particularly when safety data is involved or when your study is approaching a key milestone for data reporting (e.g. interim or final database lock).

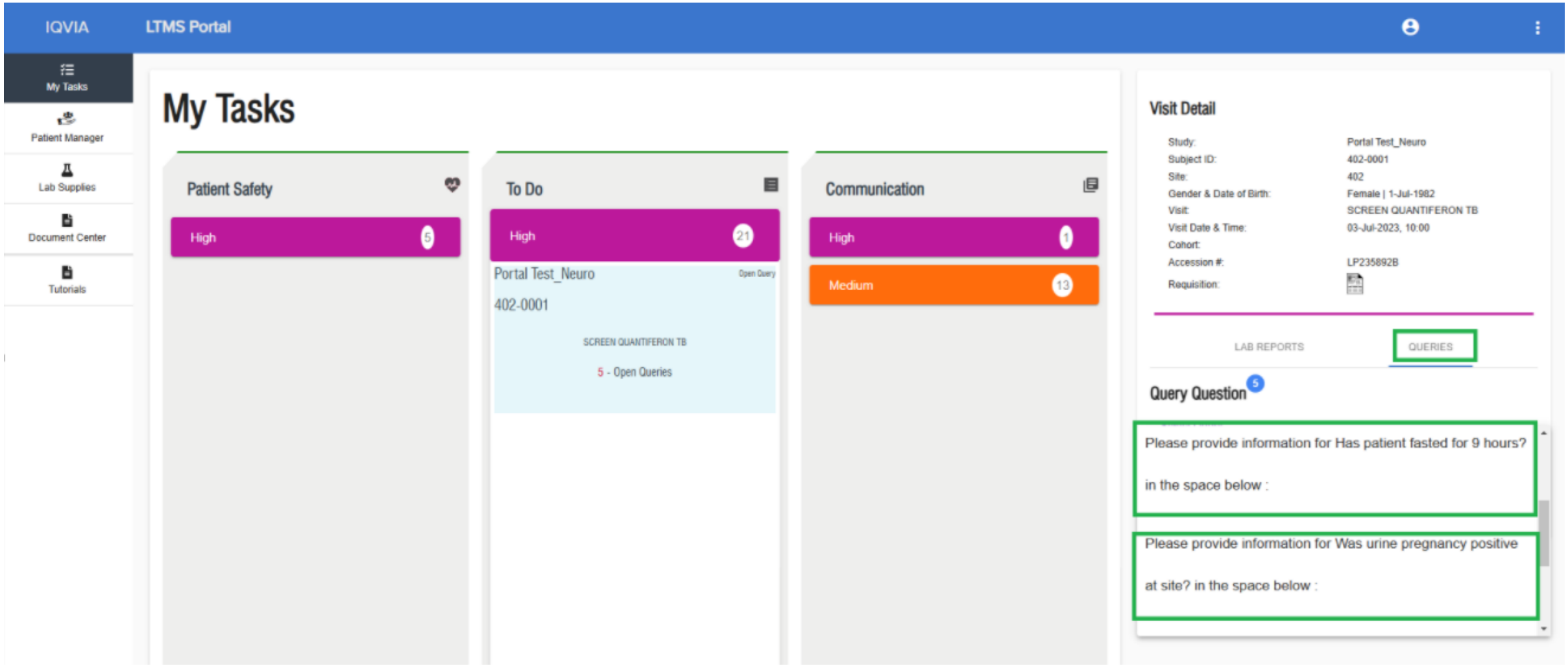
How to View and Respond to DCQs in the LTMS Portal

- Sites staff should monitor and respond to queries via LTMS Portal so it can be sent to IQVIA Laboratories for us to resolve the queries and expedite delivery of the lab reports. It allows users to view all open queries in one location when viewing or clarifying queries over phone calls with Investigator Site Support Team.

- Site staff can respond to data queries by selecting (1) “My Tasks” and then click on “To-Do” (2), select the protocol, refer to subject and visit information populated at (3). Users can further navigate to Queries (4), to view and respond to a query associated with the visit. To access Lab reports, select (5).

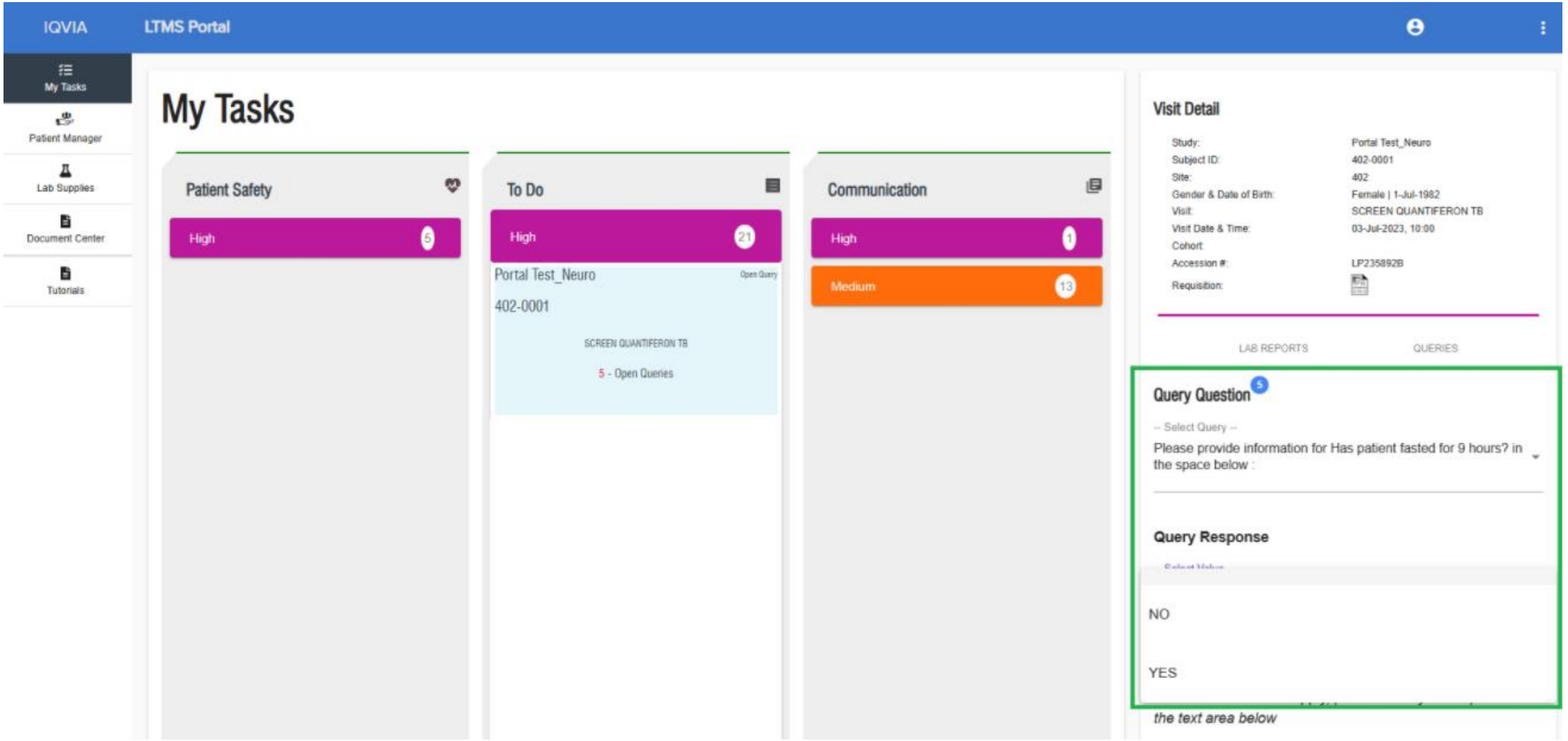


How to View and Respond to DCQs in the LTMS Portal



How to View and Respond to DCQs in the LTMS Portal

- Click on the query. The query will expand below.



How to View and Respond to DCQs in the LTMS Portal

- Site users can enter a response and click submit. Repeat if there is more than one query. When all queries for a visit/accession have been answered, the notification will automatically disappear.

- After the site submits a response, the High Priority banner from “To Do” will disappear. The response is immediately sent to IQVIA Laboratories to review and resolve. If there is an issue with the site response, an IQVIA Laboratories representative will contact the site or re-issue the query back to the LTMS Portal.

- If the site is experiencing delays in receiving reports, they should contact an IQVIA Laboratories representative via the Toll-Free numbers indicated within the Lab manual and Flowchart.

- If site discovers an answer is wrong in site portal after submission, they can contact the IS team and study PM/PC directly via email/phone to correct the answer.

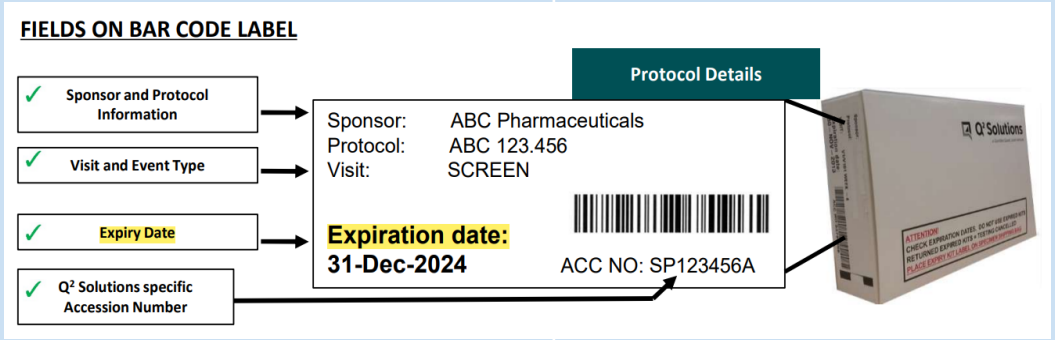
How to answer DCQs?

- Data clarifications are always communicated to the site via the LTMS Portal, email or by Telephone.
- Queries are available in the LTMS Portal for response.
- If a response is not received for a query, Investigator Site Support will attempt to contact the site directly via telephone to obtain resolution to the query.
- If the Investigator Site Support team is unsuccessful in resolving the query, this will be escalated to the Clinical Research Associates (CRA)/Sponsor via email. The project management team will also escalate these DCQs to the responsible CRA or site monitors.
- It may not be possible to issue the Laboratory Reports for a visit which has one or more DCQs until any or all DCQs have been resolved. Delays to patient results could impact patient safety.
- Sites are encouraged to contact Investigator Site Support if it is unclear what information is required to resolve a DCQ.
- Investigator Site Support contact information is available within the Lab manual, Flowchart or *IQVIA Labs Investigator Site Support - IQVIA*

IQVIA LABORATORIES

Common DCQs, Recommended Response & Best Practices

- Expired Kits

Query	Reasons	Recommended Responses/Actions	Best Practices
Please confirm if the expired tube(s) for Accession# <ACCESSION#> were replaced with non-expired tubes for sample collection.  	• Expired kits were used • Spare labels were not used	**The expired tube was replaced** • Confirming the replaced tube was taken from Standard Bulk Supply Box and providing the new expiration date on label • Providing the new accession number on the replaced tube **The expired tube was not replaced - Testing will be cancelled** • Confirming the expired tube was not replaced • Providing the disposal plan for the expired tube	• Check expiration date on the label of the kit packaging. This shows the earliest expiration date of all tubes within the kit. • Regularly check the kit storage and the expiration date. Expiry date of individual tubes should be visible on the manufacturers label, where applicable. • We strongly recommend that sites discard kits containing expired tubes. However, if that is the only kit site have at patient visit, the expired tubes should be replaced with non-expired tubes from the bulk supply kit. Ensure that all replacement tubes are properly labeled using the spare labels provided within the lab kit. Before packing tubes for shipping, please check that all tubes have matching accession (barcode) number corresponding to the requisition form in use. • Please remember to conduct regular inventory checks of lab kits and place orders in advance to prevent potential kit shortages.

Common DCQs, Recommended Response & Best Practices

- ADT Question

Query	Reasons	Recommended Responses/Actions	Best Practices
Please confirm answer for <ADT> as data was not indicated on requisition form.	• Site did not provide the required administrative details on the req form • Unclear information - handwritten answers/comments are difficult to interpret	• Confirmed that the correct <ADT> is _____.	• Each ADT question on the requisition form is required. • All provided information must be clear and legible.
	• The req form was not sent with the samples	• Send a scanned copy of the req form to ISS team via E-mail • ISS email address is available within the Flowchart and IQVIA Labs Investigator Site Support – IQVIA.	• The white copy of req form should be sent to IQVIA Laboratories along with the first shipment of samples. • The yellow copy of req form should be retained on site.

Common DCQs, Recommended Response & Best Practices

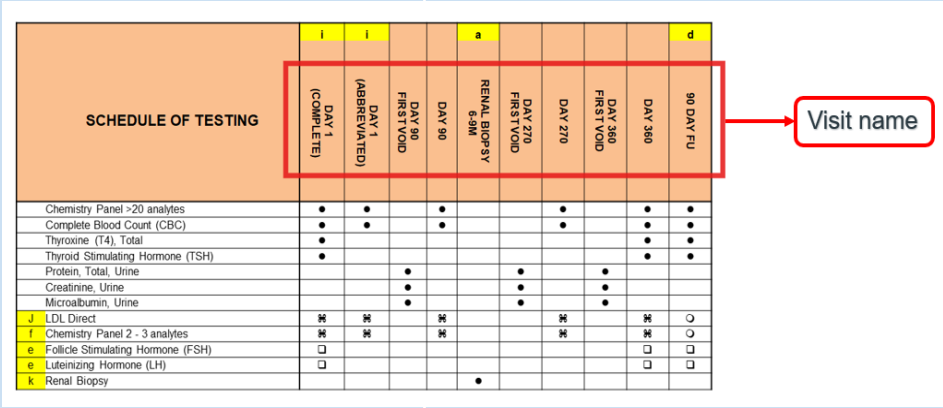
- ADT Question

Query	Reasons	Recommended Responses/Actions	Best Practices
Please confirm answer for <ADT> as data was not indicated on requisition form.	• Using U/R or other scheduled kit for sample collection and the visit name on the req form was modified. - In such cases, the sample will be accessioned into the database according to the updated visit name. - Query will be raised if the mandatory ADT question is either missing or not marked on the received req form.	**When using an alternative lab kit, please follow the steps below to obtain a new req form:** 1. Contact ISS team via email /hotline before the sample collection 2. Provide the original accession# on the req form/tube label and request the new created req form in the correct visit 3. Download, print and fill in all mandatory fields accurately 4. Ensure the accession# on the req form matches the accession# on the tube label 5. Ensure that any change on the req form is stated with the signature, date and name of the responsible person to provide traceability. 6. Return the printed req form with the sample to IQVIA Laboratories	• Ensure all ADT questions are completed to maintain data integrity. • Pending ADT questions may impact sample testing and lab report released. • Regularly monitor kit storage and expiration dates to confirm proper storage conditions and validity of kits. • Destroy the expired kits on site and reorder them as needed to avoid impacting sample collection and testing.

Common DCQs, Recommended Response & Best Practices

- Visit Section

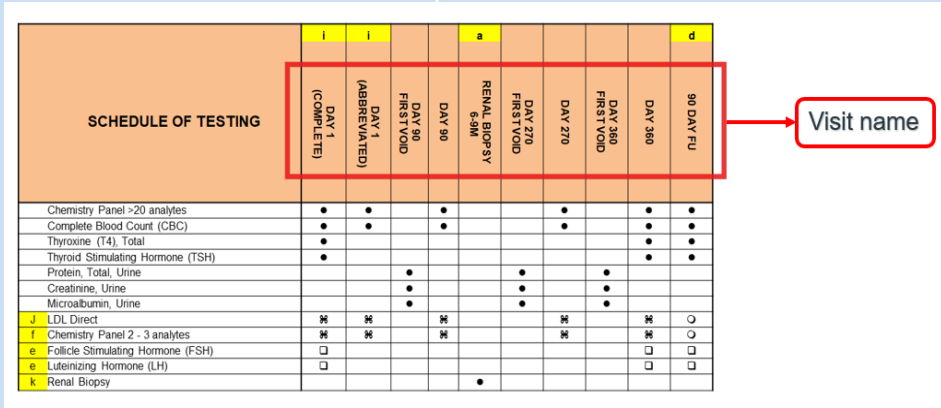
Query	Reasons	Recommended Responses/Actions	Best Practices
This is not the next sequential visit. Please clarify if visit name indicated on the requisition form is correct. This query is raised due to missed visit (s) in patient history.	• **Missing next scheduled visit** - Not received Visit 2 before Visit 3	• Please confirm if all scheduled visit samples were collected. • Please refer to the LABORATORY EVENT SCHEDULE shown in the study-specific Flowchart for the full visit name and select the correct visit name. The visit name in the Protocol may differ from the study-specific Flowchart. Please ensure the selected visit name matches the one on the Flowchart.	• If no available visit name can be selected, please contact ISS team via email /hotline to confirm visit name. • Investigator Site Support contact information is available within the Flowchart and [IQVIA Labs Investigator Site Support – IQVIA].
Please clarify if visit indicated on the requisition form is correct. This query is raised due to missed visit (s) in patient history.			
Please clarify if visit name indicated on the requisition form is correct. This query is raised because the next scheduled visit for this subject has already been received. The visit history of the subject is out of sequence.	• **Out of Sequence Visit** - Current subject visit provided does not match the expected subject visit (e.g. Visit 3 received before Visit 2)		
Please clarify the correct visit name as the subject has completed this visit before. If this is an Unscheduled/Retest visit, please also confirm tests required.	• **Duplicated Visit** - Current visit already exists in the database under a different accession number.		



Common DCQs, Recommended Response & Best Practices

- Visit Section

Query	Reasons	Recommended Responses/Actions	Best Practices
Please provide visit name as it is missing on the sample label <ACCESSION #> <Tube description>.	• Visit name not indicated on the tube label • The provided visit name was incomplete • Visit name not modified when replacement tube was used	• Please confirm if all scheduled visit samples were collected. • Please refer to the LABORATORY EVENT SCHEDULE shown in the study-specific Flowchart for the full visit name and select the correct visit name. The visit name in the Protocol may differ from the study-specific Flowchart. Please ensure the selected visit name matches the one on the Flowchart.	• If no available visit name can be selected, please contact ISS team via email /hotline to confirm visit name. • Investigator Site Support contact information is available within the Flowchart and IQVIA Labs Investigator Site Support – IQVIA.



Common DCQs, Recommended Response & Best Practices

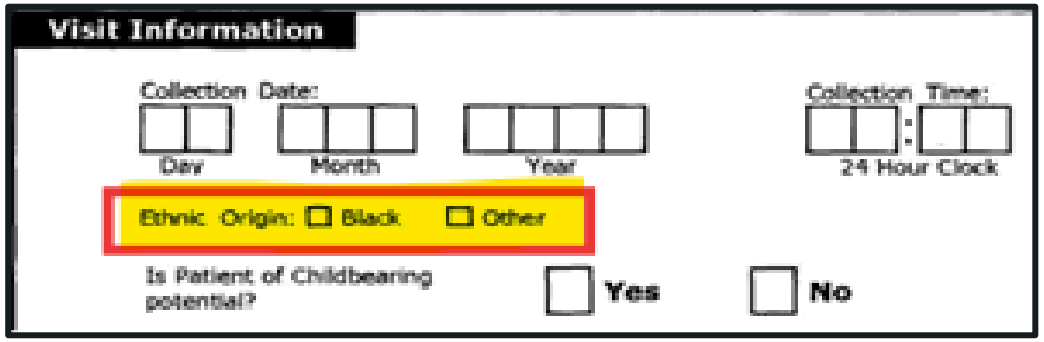
- Subject Section

Query	Reasons	Recommended Responses/Actions	Best Practices
SCREEN ID <SCREEN_ID> is already assigned to another subject at site. Please clarify correct SCREEN ID.	• The lab kit was used from other sites, but the pre-printed site number on the requisition form was not modified. • The subject demographic information on the requisition form does not match the database.	 • **Correct Examples** SCR-999999-999 ✓ • **Avoid** 999999-999 ✗ 999 ✗	• If using kits from other sites, please revise the preprinted content on the req form to reflect accurate and consistent information. • Screen ID / Patient ID should be provided in the format specified on the requisition form, including the preprinted content.
Patient ID <PATIENTID> is already assigned to another subject at site. Please clarify correct Patient ID.		 • **Correct Examples** 999999-999 ✓ • **Avoid** 999 ✗	

Common DCQs, Recommended Response & Best Practices

- Subject Section

Query	Reasons	Recommended Responses/Actions	Best Practices
Subject's Ethnic Origin was not indicated on Lab requisition. Please clarify subject's Ethnic Origin.	• Subject's ethnic origin not indicated on the req form (e.g. site uses other visit kit) • Font and checkbox for Ethnic origin is small and is easily missed out	• Indicated that the subject's ethnic origin is OTHER, BLACK or provide in free text. • This question is mandatory and the answer need to be provided for laboratory test calculation.	• The subject's ethnic origin will affect the calculated test results.



Common DCQs, Recommended Response & Best Practices

- Sample Section

Query	Reasons	Recommended Responses/Actions	Best Practices
Please confirm if collection date (DD/MM/YYYY) indicated on requisition form is correct. Sample received at IQVIA Laboratories more than 3 days after indicated collection date. The stability of the submitted specimen may be in question.	• **Warning notification** - The sample stability exceeded based on the collection date provided on the requisition.	• Fill in date of sample collection in the format of **DD** (Day)/**MMM** (Month)/**YYYY** (Year).	• All provided information must be clear and legible. • Complete the req form during the subject visit - do not prefill it. • Ensure the provided information match the site records. • Ensure that any change on req form is stated with the signature, date and name of the responsible person to provide traceability. • Refer to flowchart for shipping frequency and courier last call by/last pick up time for courier availability. • During festive season, refer to holiday memo to ensure courier availability.
Please clarify collection date (DD/MM/YYYY) as data on requisition form is unclear.	• **Illegible Handwriting** - The handwritten information are nonstandard and difficult to interpret. • **Unauthorized Modification** - Collection date was changed without proper documentation, including the signature, date and name of the responsible person.		
Please provide collection date (DD/MM/YYYY) as date on requisition form is not provided.	• **Information Not Provided** - The question was overlooked.		

Common DCQs, Recommended Response & Best Practices

- Block ID

Query	Reasons	Recommended Responses/Actions	Best Practices
Please provide information for ORIGINAL BLOCK ID as data was not provided on requisition form.	• **Information Not Provided** - The question was overlooked.	Block ID is _____.	• Original block ID indicated on the requisition form must match Original block ID on the material submitted. **Note:** • Block is considered as primary specimen. Block ID is the unique sample identifier assigned at the hospital after a tissue block is collected from the subject. Every tissue collected should have an unique identifier. • Slides are considered as secondary specimen and must be traceable back to the primary specimen. • All samples under one accession# must come from the same block.
Please clarify information for ORIGINAL BLOCK ID as data on requisition form is unclear.	• **Illegible Handwriting** - The handwritten information are non-standard and difficult to interpret. • **Unauthorized Modification** - Block ID was changed without proper documentation, including the signature, date and name of the responsible person.		

Common DCQs, Recommended Response & Best Practices

- Block ID

Query	Reasons	Recommended Responses/Actions	Best Practices
• Received <number of slides / block> slides with Block ID <Block ID number> mismatch the Block ID <Block ID number> on the requisition form. Please confirm the correct Block ID. • Received <number of slides / block> with Block ID <Block ID number> and <number of slides / block> with Block ID <Block ID number> mismatch the Block ID <block ID number> on the requisition form. There should be only 1 Block ID. Please confirm the correct Block ID. • Received <number of slides / block> with no Block ID mismatch the Block ID <Block ID number> on the requisition form. Please confirm the correct Block ID. • Blank indicated for block ID on the requisition form but we received <number of slides / block> with block ID <Blcok ID number>.Please confirm the correct Block ID.	• The Block ID provided appears to be inconsistent.	Block ID is _____.	• Original block ID indicated on the requisition form must match Original block ID on the material submitted. **Note:** • Block is considered as primary specimen. Block ID is the unique sample identifier assigned at the hospital after a tissue block is collected from the subject. Every tissue collected should have an unique identifier. • Slides are considered as secondary specimen and must be traceable back to the primary specimen. • All samples under one accession# must come from the same block.

Common DCQs, Recommended Response & Best Practices

- Slide Preparation Date & Date of Biopsy/resection

Query	Reasons	Recommended Responses/Actions	Best Practices
The collection date entered into system should be as same as Date of biopsy/resection on the req form however site blank indicated Date of biopsy/resection on the req form,please confirm correct collection date.	• **Information Not Provided** - The question was overlooked.	• Fill in date of sample collection in the format stated in the requisition form e.g. **DD** (Day)/**MMM** (Month)/**YYYY** (Year).	• **Use leading zeros** - To ensure clarity and avoid ambiguity, always write dates with two digits days and months, even if the value is below 10 (e.g., 01/09/2025 instead of 1/9/2025). • **Correct Examples:** 01/09/2025 (01Sep2025) ✓ • **Avoid:** 1/9/2025 (ambiguous - could be 01Sep2025 or 09Jan2025) ✗ 01/9/2025 (inconsistent format) ✗
The collection date entered into system should be as same as Date of biopsy/resection on the req form however site indicated non-standard Date of biopsy/resection on the req form,please confirm correct collection date. (*verbiage may vary)	• **Illegible Handwriting** - The handwritten information are non-standard and difficult to interpret. • **Unauthorized Modification** - Biopsy date/Slide section date was changed without proper documentation, including the signature, date and name of the responsible person.		

Common DCQs, Recommended Response & Best Practices

- Slide Preparation Date & Date of Biopsy/resection

Query	Reasons	Recommended Responses/Actions	Best Practices
The collection date entered into system should be as same as Date of biopsy/resection on the req form however Slide preparation date earlier than Date of biopsy /resection,please confirm correct collection date.	**Misunderstanding in date definitions** 1) Date of Biopsy/resection - The actual date when the tissue sample was collected from the subejct via biopsy or surgical resection. 2) Slide preparation date - The date when the tissue sample was processed, embedded and sectioned to create microscope slides.	• Fill in date of sample collection in the format stated in the requisition form e.g. **DD** (Day)/**MMM** (Month)/**YYYY** (Year).	• **Flag discrepancies** - Slide preparation date must be later than Date of Biopsy/resection. • The provided information must be pulled from surgical records or pathology report.
The collection date entered into system should be as same as Date of biopsy/resection on the req form however site indicated future Date of biopsy/resection on the req form,please confirm correct collection date.			
The Collection date entered into system should be as same as biopsy collection date on the req form however Date of slide sectioning at site earlier than biopsy collection date,please confirm correct collection date.			