ACL Laboratories
Every Sample is a Life™

Test Bulletin

July 2018

Quantiferon-TB Gold Plus, Blood (Test Order Code QUANTP) Test Update

Effective Wednesday July 18, 2018, ACL Laboratories will transition to a new 4 tube Quantiferon-TB Gold Plus (Test Order Code QUANTP) test. The current 3 tube, Quantiferon-TB Gold (Test Order Code QUANTB) test will be discontinued and the associated collection kit should **NOT** be used for collection of specimen on or after **Wednesday, July 18, 2018.**

Quantiferon-TB Gold Plus uses the same test principle, procedures, and technology as the current test with the exception of the fourth collection tube. Quantiferon-TB Gold Plus now includes antigens to elicit an Interferon (IFN) production response from both CD4+ and CD8+ T cells, providing a more comprehensive assessment of cell mediated immune response to TB infection.

The previous generation test only tested the CD4+ response. Published studies have shown that CD8+ T cells help to better distinguish active from latent TB, differentiating recent **versus** old infections, detecting TB infections in HIV co-infection and young children, and assessing response to TB treatment. The Quantiferon-TB Gold Plus has a sensitivity of > 97% and a specificity of > 94%, producing more accurate results than the previous test. In addition, fewer "indeterminate" results have been observed.

With the exception of collection of a fourth tube, there are **NO** changes in specimen processing and handling:

- Specimens ***must*** be transported **UNCENTRIFUGED** at Room Temperature.
- Specimens ***must*** be received at one of the three processing sites ACL Wisconsin Central - West Allis, Aurora Baycare Medical Center - Green Bay, and ACL Illinois Central - Rosemont within 14 hours of collection.
- Updated specimen collection instructions will be included in the new collection kits and the ACL Directory of Services for the new Quantiferon-TB Gold Plus (Test Order Code QUANTP).

Prior to Wednesday July 18, 2018, a flyer outlining the change will be included in all Quantiferon kits supplied by ACL Laboratories. In addition, the new 4 tube Quantiferon collection kits can be ordered through ACL Laboratories Supply Department starting July 1, 2018. To reiterate:

- Three (3) tube kits ***must*** be used ***until*** July 18, 2018.
- Four (4) tube kits ***must*** be used for any collections ***on or after*** July 18, 2018.

If you have any questions, please consult the ACL Laboratories Directory of Services at https://www.acllaboratories.com/test-catalog/ or contact ACL Laboratories Client Services at 1.800.877.7016.

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ACL Implements New Policy for Handling Specimens with Non-ACL Requisitions

Effective Monday, July 16, 2018, ACL Laboratories will implement a new policy for handling specimens submitted with non-ACL requisitions. ACL strives to identify and reduce patient safety risks and we stand by our belief that "Every Sample is a Life™". Some of the risks associated with handling patient specimens submitted on non-ACL requisitions are identified below.

- Forwarding specimens to other laboratories can delay getting results to the provider by a minimum of 1-2 days.
- Specimen integrity can be compromised.
- Patients do not understand why, if they choose to go to an ACL Patient Service Center, and have a non-ACL requisition, there will be a delay in their provider receiving their laboratory results.

To minimize patient safety risks and optimize specimen integrity and the timely performance and reporting of laboratory test results, ACL Laboratories will perform all testing that is placed in an ACL lockbox or delivered to ACL on a non-ACL laboratory requisition.

ACL will order the testing as written on the non-ACL requisition and contact the provider with any questions. Testing will be performed and the patient's laboratory results will be sent to the provider. Billing will be based on the information included on the non-ACL requisition.

Frequently Asked Questions:

Q. Why is ACL Laboratories making this change?

We have identified several patient safety issues with the current process of sending patient specimens with non-ACL requisitions to another laboratory, including delay in patient results and potential for adverse effects on specimen integrity.

Q. What do you mean by non-ACL requisition?

This includes outside laboratory requests on another laboratory's requisition or outside laboratory requests on a prescription order.

Q. How will ACL know what to order?

Our Phlebotomists and Specimen Processors are trained to ensure the test(s) ordered on the non-ACL requisition is matched to the correct test in ACL's test menu. If there are any questions or further clarification is required, our team will contact the ordering provider to verify the laboratory test orders.

Q. What if ACL does not perform the particular test(s) the provider is requesting?

Any testing ACL does not perform will be sent out to one of our reference laboratory partners for test completion.

Q. What if my patient insists on sending to another laboratory?

If your patient does ***not*** want ACL Laboratories to perform the laboratory testing, then your patient ***must*** make sure they do ***not*** visit an ACL Patient Service Center to have their laboratory services performed. If a specimen is collected in the office and patient insists sending to another laboratory, then it should not be left in the ACL lockbox. Please refer to ACL Laboratories accepted insurance list (https://www.acllaboratories.com/patient-info/insurance-providers/) to help with the decision. In most cases, ACL Laboratories accepts the insurance and specimens do not need to go to another laboratory.

Q. Who will ACL bill for laboratory testing?

ACL will bill based on the information provided on the non-ACL requisition. If commercial insurance is indicated on the non-ACL requisition, ACL will bill the insurance company. If Client bill is indicated, ACL will bill the provider/client. A complete listing of insurances can be found at https://www.acllaboratories.com/patient-info/insurance-providers/

Specimen Identification and Labeling

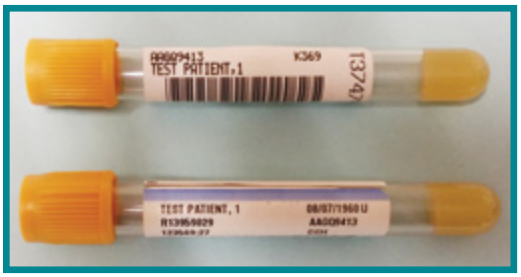
All specimens submitted to ACL for testing **must** be appropriately labeled. This requirement assures positive identification and optimum integrity of patient specimens from time of collection until testing is completed and results are reported. Clients will be notified of inappropriately labeled specimens. Unlabeled or incompletely labeled specimens will **not** be tested (see Specimen Rejection Criteria below).

Specimen Labels

Proper positioning of the patient label is important for automated analyzers. If not positioned properly, results could be delayed.

- Patient labels need to be positioned directly below the tube cap.
- For 13 x 75 tubes: Hold tube horizontally with the cap facing left. Align the patient label as close to the top of the cap as possible.

- For 13 x 100 tubes: Hold the tube horizontally with the cap facing left. Align the patient label with the top of the manufacturer's label on the tube. (no higher)



- If your patient label is >2 inches long, you will need to trim the label to fit properly on the 13x75 tube. **DO NOT wrap label to bottom of the tube.**

The College of American Pathologists (CAP) requires that primary specimen containers are labeled by at least **2 identifiers** (CAP GEN.40491).

1. The patient's name (full last name, then full first name) is **always** required.

2. The second patient identifier may be one of the following:

   - Date of birth (month/date/year)
   - Other unique patient identifier that is also on the test requisition, e.g., hospital or patient ID code or file number
   - ACL requisition number or specimen barcode label
   - Other barcode labels can be used if barcode matches the unique identifiers on the printed requisition (the barcode does not need to be human readable)

Each specimen must have a securely affixed label with the following information:

- The patient's full name written exactly as it appears on the test requisition (e.g., Doe, Jane)
- A second patient identifier as noted above
- Date and time of collection

If the label is hand-written, use a ballpoint pen–do **not** use a felt tip pen. If glass slides are submitted, use a pencil for labeling the frosted end–two identifiers are preferred although patient's name alone is acceptable.

When using an electronically generated ACL Laboratories test requisition, place the label lengthwise on the tube.

Transfer tubes: When submitting a specimen in a container other than the tube used to draw the sample (e.g., transfer vials), also indicate specimen type on the label (e.g., serum, plasma, urine, etc.).

Cultures: When submitting specimens for microbiological testing (e.g., cultures, bacterial antigen, microscopic examination), for non-blood specimens, the anatomic source of the sample and the specific organism(s) to be detected, if any, should be specified.

Surgical Specimens: Include patient name, date of birth, age, sex, physician name and location, specimen type or source. All required information **must** be on specimen container itself, **NOT** the lid.

Cytology Specimens: Include patient name and second identifier (i.e., DOB) on the specimen container. Source **must** be identified on the requisition along with the patient name, date of birth, sex, physician name and location. Including the last menstrual period is strongly recommended.

Specimen Rejection Criteria

Unlabeled or incompletely labeled specimens will **not** be tested. If the sample type is considered irretrievable, an Irretrievable Form will be sent to the provider to complete in order for the specimen to be processed. When ACL Laboratories receives a properly completed Irretrievable Form, the specimen will be processed. Completed forms that have not been returned within 48 hours will have specimens rejected and sent back for correction.

Specimens will be rejected and the tests and charges canceled under the following conditions:

- Unlabeled or incompletely labeled specimens
- Name on specimen does not match name on requisition or electronic order
- Leaking specimen
- Broken container
- Incorrect specimen submitted for test requested
- Insufficient volume (QNS)
- Improper specimen transport temperature
- Age of the specimen (test dependent)
- Hemolysis (test dependent)
- Specimens received with no written or electronic order

Requisitions for ThinPrep® Pap Test specimens must include:

- Complete patient demographic information (sex of patient, first and last name, DOB, and a third identifier, such as MRN, address or last four numbers of SSN)
- Date of Collection and Physician/Licensed caretaker name, address, phone and client #
- Testing requested (Pap with HPV, Pap only, Pap with TVLP, CGLP, HPV GT reflex, etc.)
- Source of specimen (cervix, vagina, endocervix)
- Last Menstrual Period information is highly recommended
- Pertinent clinical history (post-partum, post-hysterectomy etc.) is highly recommended

New Medicare Cards: Medicare Beneficiary ID (MBI) Final Reminders

Effective Sunday, April 1, 2018, the Centers for Medicare and Medicaid Services (CMS) began mailing new Medicare cards with a different ID number format.

Medicare patients are getting their new Medicare cards with new numbers known as **Medicare Beneficiary Identifiers (MBIs)**. MBIs will replace the existing Social Security Number (SSN) based Health Insurance Claim Number (HICN) on the new Medicare cards and in the systems Medicare uses now. CMS will replace all current cards and SSN-based numbers by April 2019.

Starting June 1. 2018, CMS began mailing new cards to Illinois and Wisconsin Medicare patients. Providers in these two states should start seeing the new MBIs soon.

CMS is informing Medicare patients to provide their new Medicare card when they seek medical care. It is important to protect the identity of Medicare patients by receiving and using their new MBIs as soon as possible. **NOTE:** Medicare Advantage and Prescription Drug plans will continue to assign and use their own identifiers on their health insurance cards. For patients in these plans, continue to ask for and use the plans' health insurance cards.

Listed below are three ways the new MBIs can be obtained:

1. Directly from Medicare patients: Medicare is mailing the new Medicare cards in phases by geographic location to people with Medicare. Ask Medicare patients for their new Medicare card when they seek medical care. If they have received a new card but don't have it with them at the time of service, remind them they can use **MyMedicare.gov** to get their new Medicare number.
2. Use the Medicare Administrative Contractors' (MAC's) secure MBI look-up tool: **Learn about** and **sign up** for the Portal to use the tool when it is available no later than June 2018. MBIs can be looked up for Medicare patients who don't have their new cards when they come for care.
    - **NOTE:** The MAC portal MBI look-up tool will only return an MBI if the new Medicare card has been mailed. This avoids potential confusion if the MBI is used before the beneficiary receives their new Medicare card/MBI.
3. Check the remittance advice. Starting October 2018 through the end of the transition period, Medicare will return the MBI on every remittance advice when claims are submitted with valid and active HICNs.

Railroad Retirement Board (RRB) Medicare Card Mailing:

RRB Issued Medicare Card

Starting June 1, 2018, the RRB began mailing new Medicare cards to their beneficiaries. CMS will return a message on the eligibility transaction response for every RRB patient MBI inquiry that will read, "Railroad Retirement Medicare Beneficiary."

The new RRB card will still have the RRB logo in the upper left corner and "Railroad Retirement Board" at the bottom, but you ***cannot*** tell from looking at the MBI numbers if these patients are eligible for Medicare because they are railroad retirees.

CMS has multiple resources to help with using the new Medicare cards. For additional information regarding the new MBI and specific deadlines surrounding this effort, access the link provided below:

- **Downloadable Program PDF:** https://www.cms.gov/Outreach-and-Education/Medicare- Learning-Network-MLN/MLNProducts/Downloads/TransitiontoNewMedicareNumbersandCards-909365.pdf

Change in Reporting for *Clostridium difficile* Toxin, PCR; *C. difficile* by DNA Amplification (Bay Area Medical Center Use Only); MRSA PCR Screen, *S. aureus* Methicillin Sensitive/ MRSA PCR Screen, Group B Strep by PCR, and Group B Strep by PCR with Sensitivities

Effective Wednesday, July 18, 2018, in an effort to standardize reporting of molecular testing results, ACL Laboratories will change the reporting criteria for the positive results from the following tests:

- *Clostridium difficile* Toxin, PCR (Test Order Code CDPCR)
- *C. difficile* by DNA Amplification (Test Order Code CDAMP; ***only*** available at Bay Area Medical Center)
- MRSA PCR Screen (Test Order Code MRSASC)
- *S. aureus* Methicillin Sensitive/MRSA PCR Screen (Test Order Code SAMRSC)
- Group B Strep by PCR (Test Order Code GBSPCR)
- Group B Strep by PCR with Sensitivities (Test Order Code GBPCRS)

Positive results from these tests will no longer be reported as "Positive", but rather as "Detected". This nomenclature is routinely utilized in the laboratory industry and is consistent with most other molecular tests currently performed at ACL Laboratories. Negative results are currently and will continue to be reported as "Not Detected".

For additional information regarding these tests, as well as specimen collection requirements, please contact ACL Client Services at 1.800.877.7016 or visit our website at www.acllaboratories.com/test-catalog/.

ACL Laboratories Announces Modification of Current Ordering for CoPath Oncology Tests

Effective Wednesday, July 18, 2018, ACL Laboratories will modify the following standalone oncology CoPath tests to ACL orderable only. Test order codes affected include EXRAS Mutation Analysis (Test Order Code EXRAS), NRAS Mutation Analysis (Test Order Code NRAS), KRAS Mutation Analysis (Test Order Code KRAS), BRAF Mutation (Test Order Code BRAF) and EGFR Mutation (Test Order Code EGFR). Based on ACL Laboratories Pathologists and NCCN 2017 recommendations, all single oncology orders should be ordered as Solid Tumor Mutation Panel (Test Order Code STMP15) (NGS panel).

Modifications include the following:

1. Single oncology orders will be modified to ACL orderable only.
2. Single order codes will be removed from interfaced electronic ordering systems. Clients should use Test Order Code STMP15.
3. The ACL Directory of Services entries for all modified test codes will be updated to reflect current practice.

For additional information regarding these tests, as well as specimen collection requirements, please contact ACL Client Services at 1.800.877.7016 or visit our website at www.acllaboratories.com/test-catalog/.

Inactivated Codes with Recommended Alternative Tests

Inactivated Test Order Code	Inactivated Test Name	Recommended Alternate Test Order Code	Recommended Alternate Test Name / Reference Laboratory & Test Number.
LONFAT	Long Chain Fatty Acids	REF796	Very Long-Chain and Branched-Chain Fatty Acids Profile / Cleveland Clinic Laboratories (FATLON)

Immunoglobulin D, Quantitative, Serum (Test Order Code IGDQNT)

Effective immediately, Cleveland Clinic Laboratories (CCL), the performing laboratory, has updated the specimen requirements for Immunoglobulin D, Quantitative, Serum (Test Order Code IGDQNT). Due to transportation requirements, the stability of refrigerated specimens cannot be guaranteed.

Specimen collection requirements are as follows:

Immunoglobulin D, Quantitative, Serum (Test Order Code IGDQNT)	**Current Specimen Collection Requirements**	**New Specimen Collection Requirements – *Effective Immediately***
Transport	1.0 mL (min: 0.5 mL) serum refrigerated	1.0 mL (min: 0.5 mL) serum frozen

Benzodiazepines Quantitation, Urine (Test Order Code UBNZCF)

Effective immediately, Cordant Laboratories, the performing laboratory, has removed 8 components from the test performance of Benzodiazepines Quantitation, Urine (Test Order Code UBNZCF).

Resulted components are as follows:

Current Components	New Components – *Effective Immediately*
Benzodiazepines Confirmation	Benzodiazepines Confirmation
7-Aminoclonazepam Quantitation	7-Aminoclonazepam Quantitation
7-Aminoclonazepam Result	7-Aminoclonazepam Result
7-Aminoflunitrazepam Quant	Removed
7-Aminoflunitrazepam Result	Removed
Alpha Hydroxy Alprazolam Quant	Alpha Hydroxy Alprazolam Quant
Alpha Hydroxy Alprazolam Res	Alpha Hydroxy Alprazolam Res
Alpha Hydroxy Midazolam Qt	Removed
Alpha Hydroxy Midazolam Res	Removed
Desalkyflurazepam Quantitation	Removed
Desalkyflurazepam Result	Removed
Lorazepam Quantitation	Lorazepam Quantitation
Lorazepam Result	Lorazepam Result
Nordiazepam Quantitation	Nordiazepam Quantitation
Nordiazepam Result	Nordiazepam Result
Oxazepam Quantitation	Oxazepam Quantitation
Oxazepam Result	Oxazepam Result
Alpha Hydroxy Triazolam Qt	Removed
Alpha Hydroxy Triazolam Res	Removed
Temazepam Quantitation	Temazepam Quantitation
Temazepam Result	Temazepam Result

For additional information regarding these tests, as well as specimen collection requirements, please contact ACL Client Services at 1.800.877.7016 or visit our website at www.acllaboratories.com/test-catalog/.

Barbiturate Confirmation (Test Order Code UBRBCF)

Effective immediately, Cordant Laboratories, the performing laboratory, has removed 4 components from the test performance of Barbiturate Confirmation (Test Order Code UBRBCF).

Resulted components are as follows:

Current Components	New Components – *Effective Immediately*
Barbiturate Confirmation	Barbiturate Confirmation
Amobarbital Quantitation	Removed
Amobarbital Result	Removed
Butalbital Quantitation	Butalbital Quantitation
Butalbital Result	Butalbital Result
Pentobarbital Quantitation	Removed
Pentobarbital Result	Removed
Secobarbital Quantitation	Secobarbital Quantitation
Secobarbital Result	Secobarbital Result
Phenobarbital Quantitation	Phenobarbital Quantitation
Phenobarbital Result	Phenobarbital Result

For additional information regarding this test, as well as specimen collection requirements, please contact ACL Client Services at 1.800.877.7016 or visit our website at www.acllaboratories.com/test-catalog/.

Opiate Confirmation (Test Order Code UOPICF)

Effective immediately, Cordant Laboratories, the performing laboratory, has added 4 components to the test performance of Opiate Confirmation (Test Order Code UOPICF).

Resulted components are as follows:

Current Components	New Components – *Effective Immediately*
Opiate Confirmation	Opiate Confirmation
Codeine Quantitation	Codeine Quantitation
Codeine Result	Codeine Result
Hydrocodone Quantitation	Hydrocodone Quantitation
Hydrocodone Result	Hydrocodone Result
Hydromorphone Quantitation	Hydromorphone Quantitation
Hydromorphone Result	Hydromorphone Result
Morphine Quantitation	Morphine Quantitation
Morphine Result	Morphine Result
Oxycodone Quantitation	Oxycodone Quantitation
Oxycodone Result	Oxycodone Result
Oxymorphone Quantitation	Oxymorphone Quantitation
Oxymorphone Result	Oxymorphone Result
N/A	Norhydrocodone Quantitation
N/A	Norhydrocodone Result
N/A	Noroxycodone Quantitation
N/A	Noroxycodone Result

For additional information regarding this test, as well as specimen collection requirements, please contact ACL Client Services at 1.800.877.7016 or visit our website at www.acllaboratories.com/test-catalog/.