ACL Laboratories
Every Sample is a Life™

Test Bulletin

June 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 specimenon 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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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.

Currently, Illinois and Wisconsin beneficiaries are scheduled to receive their new cards after June 1, 2018. However, any beneficiary new to Medicare after April 1 will receive a new card with the MBI.

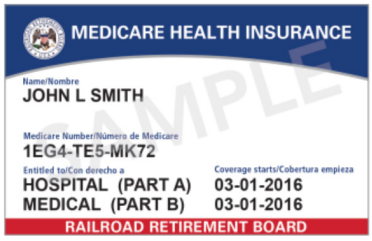
CMS is informing Medicare patients to provide their new Medicare card when they seek medical care. It is important to protect the identity of Medicare patients by receiving and using their new MBIs as soon as possible. **NOTE:** Medicare Advantage and Prescription Drug plans will continue to assign and 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.

Here are three ways the new MBIs can be obtained:

- 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.
- 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.
- 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



On June 1, 2018, RRB will mail 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

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 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 accepted insurance list (below) to help with the decision. In most cases ACL 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/

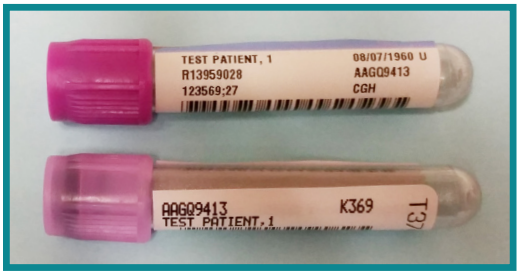
Specimen Identification and Labeling

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 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. Once properly completed form is received in the laboratory, 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

Bartonella PCR (Test Order Code BARPCR)

Effective immediately, Cleveland Clinic Laboratories (CCL), the performing laboratory, has updated the specimen requirements and test performance for Bartonella PCR (Test Order Code BARPCR).

Specimen collection requirements are as follows:

Bartonella PCR (Test Order Code BARPCR)	Current Specimen Collection Requirements	Effective immediately – New Specimen Collection Requirements
Collect	One lavender (EDTA) 3.0 mL (also acceptable: royal blue (EDTA) 3.0 mL)	One lavender (EDTA) 3.0 mL (also acceptable: one gold gel 3.5 mL and Cerebrospinal Fluid (CSF) and tissue in sterile container)
Transport	1.0 mL (min: 0.5 mL) whole blood refrigerated. Separate samples must be submitted when multiple tests are ordered. Sample should be sent in the primary collection container.	1.0 mL (min: 0.5 mL) whole blood refrigerated. Separate samples must be submitted when multiple tests are ordered. Separate plasma or serum from cells and transfer to CCL Sarstedt Aliquot Tube.
Unacceptable Conditions	Heparinized samples Bone Marrow	Heparinized samples Bone Marrow
Stability	Ambient: 7 Days Refrigerated: 7 Days Frozen: 7 Days	Ambient: Serum, plasma, CSF: 24 Hours; Whole blood: 7 Days; Tissue: Unacceptable Refrigerated: Serum, plasma, CSF: 5 Days; Whole blood: 7 Days; Tissue: Unacceptable Frozen: Serum, plasma, CSF, tissue: 1 Month; Whole blood: 7 Days
Order Remarks	This test does not differentiate between B. henselae and B. quintana.	This test does not differentiate between B. henselae and B. quintana. Specimen source is required.
Performed	Monday, Wednesday, Friday	Tuesday, Friday
Reporting Time	Final within 9 Days	Final within 7 Days

17 Hydroxypregnenolone (Test Order Code HPREG)

Effective Wednesday, June 20, 2018, Cleveland Clinic Laboratories (CCL), the performing laboratory, has updated the specimen requirements and test performance for 17 Hydroxypregnenolne (HPREG).

Specimen collection requirements are as follows:

17 Hydroxypregnenolone (Test Order Code HPREG)	Current Specimen Collection Requirements	Effective Wednesday, June 20, 2018 – New Specimen Collection Requirements
Collect	One plain red 4.0 mL (also acceptable: gold gel 3.5 mL)	One plain red 4.0 mL (also acceptable: gold gel 5.0 mL and two EDTA lavender 3.0 mL and green (lithium heparin) 6.0 mL and green (sodium heparin) 4.0 mL). Separate serum or plasma from cells within 2 hours of collection.
Transport	1.0 mL (min: 0.5 mL) serum frozen	Two 1.0 mL (min: 0.5 mL) serum or plasma aliquots frozen. Critical: Specimen must be frozen. Separate specimens must be submitted when multiple test are ordered.
Unacceptable Conditions	Unfrozen	Unfrozen
Stability	Ambient: Unacceptable Refrigerated: Unacceptable Frozen: 14 Days	Ambient: Unacceptable Refrigerated: Unacceptable Frozen: 6 Months
Performed	Tuesday, Thursday	Monday, Tuesday, Wednesday, Thursday, Friday
Reporting Time	Final within 10 Days	Final within 6 Days

JC Virus by PCR (Test Order Code JCPCRB)

Effective immediately, Cleveland Clinic Laboratories (CCL), the performing laboratory, has discontinued test JC Virus DNA, PCR CSF (Test Order Code JCPCR) and has added CSF as an acceptable sample type to JC Virus by PCR (Test Order Code JCPCRB). The CSF specific Test Order Code JCPCR will be inactivated.

Specimen collection requirements are as follows:

JC Virus by PCR (Test Order Code JCPCRB)	Current Specimen Collection Requirements	*Effective Immediately*– New Specimen Collection Requirements
Collect	One lavender (EDTA) 3.0 mL (also acceptable: Urine random)	One lavender (EDTA) 3.0 mL (also acceptable: Urine random and one gold gel 3.5 mL and one cerebrospinal fluid tube)
Transport	1.0 mL (min: 0.5 mL) plasma frozen (also acceptable: 1.0 mL (min: 0.5 mL) urine frozen)	1.0 mL (min: 0.5 mL) plasma, serum, urine or CSF frozen
Unacceptable Conditions		Heparinized specimens
Stability	Ambient: 8 Hours Refrigerated: 5 Days Frozen: 30 Days	Ambient: 8 Hours Refrigerated: 5 Days Frozen: 30 Days
Performed	Monday, Wednesday, Friday	Monday, Wednesday, Friday
Reporting Time	Final within 6 Days	Final within 6 Days

Pregabalin (Test Order Code PBALIN)

Effective immediately, Cleveland Clinic Laboratories (CCL), the performing laboratory, has updated the specimen requirements and test performance for Pregabalin (Test Order Code PBALIN).

Specimen collection requirements are as follows:

Pregabalin (Test Order Code PBALIN)	Current Specimen Collection Requirements	*Effective immediately*– New Specimen Collection Requirements
Collect	One plain red 6.0 mL. Centrifuge within 2 hours of draw and transfer to CCL's Sarstedt (primary), Non-Sterile Aliquot tube.	One plain red 6.0 mL (also acceptable: one EDTA lavender 3.0 mL) Centrifuge within 2 hours of draw and transfer to CCL's Sarstedt (primary), Non-Sterile Aliquot tube.
Transport	1.0 mL (min: 0.5 mL) serum refrigerated	1.0 mL (min: 0.2 mL) serum or plasma refrigerated.
Unacceptable Conditions	Samples collected in gel tubes.	Samples collected in gel tubes. Citrate plasma.
Stability	Ambient: 28 Days Refrigerated: 28 Days Frozen: 28 Days	Ambient: 1 Month Refrigerated: 1 Month Frozen: 2 Months
Order Remarks	Trough levels are most reproducible.	Trough levels are most reproducible. Please indicate the following on the order: 1. Dose – List drug amount and include units of measure 2. Route – List the route of administration (IV, oral, etc.) 3. Frequency – How often the dose is administered (daily, weekly, as needed, etc.) 4. Type of Draw – Indicate the type of blood draw (Peak, Trough, Random, etc.)
Performed	Tuesday	Tuesday, Saturday
Reporting Time	Final within 13 Days	Final within 8 Days

Cystine Quantitative, Urine (Test Order Code UCYSTS)

Effective immediately, Cleveland Clinic Laboratories (CCL), the performing laboratory, will update the specimen requirements and test performance for Cystine Quantitative, Urine (Test Order Code UCYSTS).

Specimen collection requirements are as follows:

Cystine Quantitative (Test Order Code UCYSTS)	Current Specimen Collection Requirements	*Effective Immediately*– New Specimen Collection Requirements
Collect	One Urine, random (also acceptable: Urine 24hr)	One Urine, 24 hour (also acceptable: Urine, timed). Please note collection period and total volume when submitting sample.
Transport	8.0 mL (min: 3.0 mL) urine frozen **CRITICAL: Specimen must be frozen.** Separate samples must be submitted when multiple tests are ordered.	4.0 mL (min: 3.0 mL) urine frozen **CRITICAL: Specimen must be frozen.** Separate samples must be submitted when multiple tests are ordered.
Unacceptable Conditions	Refrigerated or room temperature specimens.	Room temperature specimens. Refrigerated specimens that were dropped off and received greater than 1 hour of the end of the collection.
Stability	Frozen: 1 Month	Frozen: 1 Month Specimens dropped off that were refrigerated and received within 1 hour of the end of the collection are acceptable and should not be rejected.
Required Information	Provide clinical information along with age, gender, diet, drug therapy and family history. Record total volume and collection time.	Provide clinical information along with age, gender, diet, drug therapy and family history. Record total volume and collection time. Submit Patient History Form for Biochemical Genetics with sample.

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.
UIODR	Iodine, Urine	REF791	Iodine, Urine / Cleveland Clinic Laboratory (UIODNE)
PANCP	Pancreatic Polypeptide	REF794	Pancreatic Polypeptide / ARUP Laboratories (0099436)
TOXOCR	Toxocara Antibody, IgG by ELISA	REF795	Toxocara Antibody by ELISA / ARUP Laboratories (3000472)