



# Clinical 3.0 Expansion Training

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# CLINICAL OVERVIEW

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## Test Menu Changes

# Clinical Labs 3.0

- TB testing via QuantiFERON-TB Gold Plus
  - Common requirement for treatment programs & recommended in SUD population
  - Single visit (unlike skin test)
- Hepatitis C – **Quantitative** PCR
  - Common request to monitor HCV treatment effect
  - Replaces current **qualitative** HCV PCR test
- Fibrosis-4 (FIB-4) Index: Non-invasive liver fibrosis test
  - Patients with HCV/HBV/HIV dx at ↑ risk for liver fibrosis; useful screening tool to rule out biopsy need
  - Recent AASLD guidelines recommend FIB-4 Index over FibroSure: similar effectiveness, lower cost

# Additional Updates

- Following tests removed due to low utilization
  - 07113: HIV-1 Qualitative PCR
    - HIV Ab/Ag Screen & Antibody differentiation remain
  - 07131 CFM: HBsAg **Confirmation**
    - HBsAg Screen remains (included in Acute Hep & Hep B Screen Panel)
  - 07155: Free PSA
    - Total PSA remains
- Reporting comments will be updated to reflect need for additional testing (as needed)

# LOGISTICS

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Ordering, Supplies, Shipping

# Supplies

- Hep C quant and Fib-4 tests – no new supplies
- TB test:
  - Green top
  - Large ice pack (24 ounce)
    - Freeze best if placed on the floor of the freezer
  - 2 package options to insert into FE/UPS box (“Kangaroo mailer <sup>TM</sup>”)
    - Small – 1 patient for the day who needs TB testing
    - Large – 2-5 patients
    - More than 5 patients for TB testing – 2 large packages

# Pictures – TB Supplies

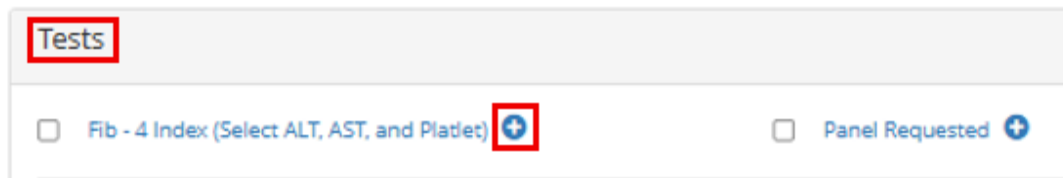


# Ordering

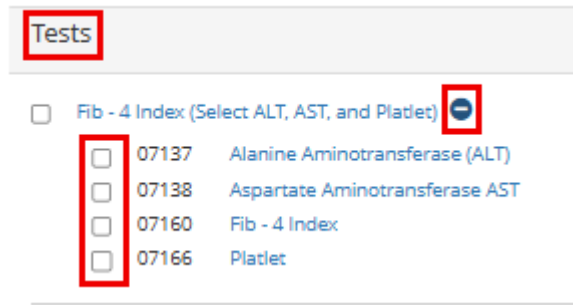
- #07160 FIB-4 Index needs 4 components for calculation: Age, Platelets, and ALT & AST
  - Platelets component of #07007 and #07008 CBC
  - ALT and AST component of #07003 CMP and #07005 Hepatic Function Panel
  - Requires **lavender** and **gold** top
- #07232 Hepatitis C quant PCR...previous test code (#07132) for qualitative test deactivated
- #07159 TB-Quantiferon-TB Gold Plus

# Ordering Fib-4 Index

- Under the 'Tests' section in CareEvolve, select the 'plus sign' to the right of 'Fib-4 Index' to expand:



This screenshot shows the 'Tests' section of the CareEvolve interface. A red box highlights the 'Tests' header. Below it, the option 'Fib - 4 Index (Select ALT, AST, and Platlet)' is displayed with a plus sign icon to its right, which is also highlighted by a red box. To the right of this option is a 'Panel Requested' checkbox and a plus sign icon.



This screenshot shows the 'Tests' section with the 'Fib - 4 Index' option expanded. A red box highlights the 'Tests' header. Below it, the 'Fib - 4 Index (Select ALT, AST, and Platlet)' option is shown with a minus sign icon to its right, highlighted by a red box. To the left of the expanded list, a vertical column of four checkboxes is highlighted by a red box. These checkboxes correspond to the following items:

| Test Code | Test Name                      |
|-----------|--------------------------------|
| 07137     | Alanine Aminotransferase (ALT) |
| 07138     | Aspartate Aminotransferase AST |
| 07160     | Fib - 4 Index                  |
| 07166     | Platlet                        |

# Collecting

- Hep C quant no change (gold)
- FIB-4 – **gold** + **lavender** – **both required**
- TB – one green top
  - Order of draw remains very important:
    - **Red/Gold/Green/Lavender**
  - Full tube needed: 6 mL tube...5 mLs is minimum
  - Process similar to lavender top:
    - Inversion step important
    - No centrifuge step
  - Refrigerate until ready to package and ship

# TB Packaging/Shipping

- 1 specimen bag per patient – all labeled tubes (**lavender**, **gold**, **red** (serum transfer tube only), **green**) for the same patient should be placed in one specimen bag
- ELR label to go on outside of specimen bag
- Remove air from bag by rolling up and then seal ziplock closed
- Place frozen ice pack vertically in kangaroo mailer
- Place specimen bag in kangaroo mailer, important to be touching the ice pack

# TB Packaging/Shipping

- Peel adhesive strip of kangaroo mailer and seal bag closed
- Puncture kangaroo mailer
  - 4 puncture points, 2 on each side
  - Fine point pen works best to get through the plastic layer
  - Kangaroo mailer should start expanding immediately...2-3 minutes to fully expand
- Once mailer is fully expanded, ready to place inside FE/UPS box
- One small mailer + 3-4 insultotes should fit in one FE/UPS box
- One larger mailer + 1-2 insultotes should fit in one box
- Should also be room for urine samples

# TB Packaging/Shipping



# Best Practices for TB

- Ice packs
  - Freeze 2 large ones at a time
  - Place side by side on floor of freezer (don't stack)
  - Check freezer setting if ice packs are not fully freezing overnight, may need to lower the temperature
  - Should also be room in freezer for 2 of the smaller ice packs
- Ship same day as collected
  - TB samples not shipped same day will be cancelled
- No Saturday collections
- No day before holiday collections
- 4 main things will result in TB testing cancellation:
  - Not in green top
  - Not full (minimum 5 mLs)
  - Not in proper packaging (including large ice pack)
  - Not shipped same day/received next day

# Reporting

- No changes with existing reporting format
- Expected TAT:
  - FIB-4: 24 hours
  - Hep C Quant PCR: 1-3 days depending on date received
  - TB-QuantiFERON: 2-5 days depending on date received
- Results report once all testing has completed
- Reporting to the individual state Department of Health guidelines:
  - We are required to report “positive” TB results to many state health departments, in addition, a few states also require reporting of all results
  - Health care providers are also required to report and often times their requirements are stricter since they are providing treatment

# Safety

- A Safety LMS module has been created
  - Important to complete as soon as possible once assigned
- TB is a bacteria that is most commonly spread through the air when a person with active TB coughs/sneezes
- Important to wear PPE when collecting samples:
  - Disposal lab coat, safety glasses, and gloves
- Any spills should be handled with caution
- Although it is airborne, it can still be spread through accidental contaminated needlestick injuries. Important to communicate to HR if this occurs

# Resources

- Quick guide - updated one page reference sheet
- Video – captures packaging process for TB samples
- Comprehensive Collection Instructions – updated to include steps for TB. Included with every initial order of supplies
- All resources found on Aegis website under Helpful Links