Requirements for Lab Testing – FHIR

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| Testing | Order | Components | Specimens  | Results | Special Considerations |
| Comprehensive Metabolic Panel | One Order | 14 components with 3 calculated/estimated results | 1 tube serum | 14 components with 3 calculated/estimated results | All typically reported together |
|  | * 1 DataElement (D1) that defines the LOINC/CPT/Local code for the CMP and identifies all of the components expected for that test
* 1 DiagnosticRequest (O1) with a LOINC/CPT and/or local code for the CMP, status=active, authorDate = today, priority=Routine, time window could be implicit or explicit – e.g. not before Jan 1, not after Feb 28
* 1 Task (T1) with code of “please fulfill” pointing to O1 with target performer of lab, no time period information unless you want to request fulfillment in a specific timeframe distinct from the “authorized” time on the order. (Task timing must fall within time period on O1)
	+ Eventually task gets a status of accepted, then in progress
* 17 DiagnosticRequests + 1 ProcedureRequest created by lab “in fulfillment of” O1 (for individual tests + specimen draw) and/or create 17 + 1 tasks to track fulfillment of steps to draw specimen and perform tests
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| Wellness Profile | One Order | 5 panel test with 41 detailed results | Up to 4 specimens | Components + calculated results | May report only partial results if unable to perform all panel tests |
|  | * 1 DataElement (D1) that defines the LOINC/CPT/Local code for the Wellness Profile and identifies all of the panels expected for that test
* 5 Data Elements (D2-D6) that defines the LOINC/CPT/Local code for each panel
* 1 DiagnosticRequest (O1) with a LOINC/CPT and/or local code for the “Wellness Profile”, authorDate = today, priority=routine, time window implicit or explicit
	+ No need to have DiagnosticRequests at the Panel or component level in the filler system – it may have locally persisted “holding areas” for expected results, but no need for exchangeable result instances for those “holding areas”
* 1 Task (T1) with code of “please fulfill” pointing to O1 with target performer of lab. Eventually the task gets a status of accepted, then in progress
* Lab creates 5 DiagnosticRequest instances LO1-LO5 – one per panel - with a “fulfills” relationship to O1 (optional)
* Lab creates either 1 DiagnosticReport and 5 Observations or 5 DiagnosticReports
* Lab creates N Task instances – based on how the test workflows are typically done (panels generally align with workflow, but not necessarily) –with a component relationship to T1 and pointing to the Lab orders each task is related to
* The tasks have sub-tasks identifying what specimens need to be collected and what tests should be done as part of each workflow
* Lab creates 4 ProcedureRequests (PR1-4) for the specimens to be drawn, with an “in fulfillment of” relationship to O1 (and possibly to one or more of LO1-5). Specimens needed will be driven by equipment, required volume, etc. Will vary by type of patient as well.
* Lab creates 1 Task T2 seeking fulfillment of PR1-4
* Observation instances will be created for each component test and will be aggregated into the observations/diagnostic reports for each panel
* DiagnosticReports will be sent to the placer system when requested or as appropriate based on normal/abnormal results, reporting periods, etc.
 |
| ACTH Stimulation | One Order | 3 components baseline, 30 min and 60 min post stimulation Observation done by reference lab | 3 specimens | Result of each test + time for each draw post stimulation | All must be performed  |
|  | * 1 DiagnosticRequest with LOINC or other code for ACTH
* 1 Task seeking fulfillment
* Lab may create child tasks and possibly child DiagnosticRequests for each test (with relative timing dependencies declared)
* Each needed Specimen has a ProcedureRequest for the blood draw and possibly a corresponding Task to track that workflow
* One MedicationRequest for the administration of the corticosteroid “based on” of the DiagnosticRequest
* One Procedure for each blood draw (as a component of the corresponding Observation) linked to the resulting Specimen resource with an “in fulfillment” of the DiagnosticRequest
* One MedicationAdministration showing the corticosteroid administration, also “in fulfillment” of the DiagnosticRequest as well as to the MedicationRequest
* Tasks created for fulfillment by reference lab for each blood draw. Procedure information about blood draws may be included as “inputs” for the task
* One Observation for each test result. Possibly also one Observation for the “relative time” of the post-stimulation measurements, though this could be captured as an extension on the measurement Observations.
* One DiagnosticReport that reports on all 3 Observations and will be “in fulfillment” of the DiagnosticRequest. DiagnosticReport may be updated as each of the results are processed.
	+ DiagnosticReport is linked as the output to both the reference lab task and the EMR’s task
 |
| Creatinine Clearance | One Order | Two tests + demographics + volume + collection time+ calculation  | 1 serum, 1 urine timed | Serum and urine creatinine + calculated results (based on Ht/Wt/BSA) sample condition (up to 12 “results” | Both specimens must be received and demographics supplied |
|  | * Typically, one DiagnosticRequest with a single LOINC or other code
* One task seeking fulfillment
	+ Demographics are present in Patient record
	+ Observation about race is included as an “input” to the Task
* Lab may create separate DiagnosticRequests for each of the tests (can be more than 2 – e.g. spot urine, creatinine in 24-hour urine as well as calculated results), along with child ProcedureRequests for the blood & urine collection. There may be Tasks created to manage the workflow of any/all of these.
	+ In some cases, the serum results from a recent test can be used instead of drawing a new specimen
* Procedures & Specimens are created for the blood & urine
* Observations produced for:
	+ Spot urine creatinine level
	+ Serum creatinine level
	+ Volume of 24hr urine
	+ Number of hours for 24hr urine
	+ Calculated 24hr urine rate
	+ GFR (based on gender and/or race)
	+ Creatinine clearance
* One DiagnosticReport pointing to the original DiagnosticRequest and component Observations (not all observations will necessarily be highlighted in the report as some are merely used for calculation)
 |
| BCRA with Reflex | Order one test | Based on results of BRCA 1 and 2 sequencing may reflex up to 9 additional tests | 4 ml whole blood EDTA | Known or likely pathogenic mutations unknown variants | Perform all to provide results and interp --  |
|  | * 1 DiagnosticRequest created by clinician. The DiagnosticRequest has a “stage” of “original order”. The code is for a “with reflex” BRCA 1 & 2 panel.
* 1 Task seeking fulfillment
* Lab may create a DiagnosticRequest with a stage of “filler order” and a “basedOn” pointing to the original order.
* Lab creates DiagnosticReport, linked to DiagnosticRequest and updates the Task to point to it

Scenario A* Results are negative, so no need to trigger additional orders. Task is marked as complete

Scenario B* Results meet criteria for triggering additional reflex orders. Task remains “in progress”
* Lab automatically creates additional DiagnosticRequests with a stage of “filler order” or “reflex order” (depending on whether they distinguish) with a “basedOn” relationship to the original DiagnosticRequest and a “supportingInformation” link to the original DiagnosticReport and/or Observations that are part of that DiagnosticReport
* Observations are added to the original DiagnosticReport or to an additional DiagnosticReport (or set of DiagnosticReports) for those subsequent DiagnosticRequests using the same specimen
* All DiagnosticReports are linked to the Task
* Task is marked as complete

Note: Sometimes a reflex test may trigger additional reflex tests, so there could be multiple iterations and a hierarchy of DiagnosticReports before the Task is considered Complete. |
| Culture, Aerobic Bacteria | One Order | Culture, Identification of bacteria, susceptibility  | One specimen (many different types) | Bacteria ID and susceptibilities | Identification and susceptibility are reflex – will provide preliminary results |
|  | * DiagnosticRequest is created by clinician.
	+ Must include information about the type of specimen to be tested as this can’t be inferred from the test code
	+ QuestionnaireResponse to the “Ask at order entry” Questionnaire defined as part of the lab test compendium is included as “supportingInformation” for the DiagnosticRequest
		- E.g. Source site description, specimen type
* Task is created pointing to the DiagnosticRequest
* Lab performs the culture on the submitted sample

Scenario A – no growth* DiagnosticReport is created indicating that nothing was found
* Task is updated to point to DiagnosticReport and marked as complete

Scenario B – normal, expected growth for site* DiagnosticReport is created indicating routine flora
* Task is updated to point to DiagnosticReport and marked as complete

Scenario C – potentially pathogenic organism* Separate isolate specimens created from the base specimen for each potential organism
* Additional observations done (possibly with additional sub-tasks)
	+ E.g. gram stain
* DiagnosticReport with status “preliminary” created showing initial results (e.g. gram positive cocci)
* May create reflex orders (stage = “reflex order” or “filler order” depending on system capabilities) or simply additional tasks to capture bacterial identification tests for each organism found
* Create reflex orders (stage = “reflex order” or “filler order” depending on system capabilities) for susceptibility panels for each identified organism
* Observations captured for each antibiotic for each organism, with grouping Observations per organism (numeric value + interpretation or code/text value) and/or as a combined observation stating both the organism and the antibiotic susceptibility. Each observation is linked to its respective reflex order.
	+ E.g. code=”Organism”, value=”Staphylococcus aureus”, related observation code=”Methicillin” value=”2” interpretation=”resistant” with related observation type=”qualified by”
	+ E.g. code=”???” value=”Methicillin-resistant Staphylococcus aureus” (may have “derivedFrom” relationship to preceding “Methicillin” Observation)
 |
| Tissue Pathology | One order  | Add specimen treatment, stains, immunohistochemistry, genetic testing as necessary | One to many specimens  | Diagnosis, stains, immunochem results, genetic results | Performed by multiple people and potentially at multiple locations partial reporting will most likely occur in complex cases |
|  | * Surgical pathology DiagnosticRequest is created as part of the surgical or other procedure or as part of the ProcedureRequest or the ReferralRequest
	+ referring to the Specimen created as part of the surgery/procedure
* Tasks and/or child DiagnosticRequests set up for the various steps (gross examination, sample collection, sub-sample collection, histology, slide preparation, staining, genetic testing, etc.)
	+ Sub-samples must identify the specific location and orientation they came from
	+ Child diagnostic requests may be spawned automatically as reflex tests based on prior results or be explicitly authorized by the pathologist. In either case, they will point back to the original order
 |
| WBC standing order  | One order | Single test | 1 purple cap tube | Single WBC | Repeating order with start date/time and stop date/time + repeat interval |
|  | * Single order created in the EHR by the clinician, but no fulfillment task
* The EHR automatically generates a new DiagnosticRequest for each occurrence of the repetition request. These child orders are marked as being “in fulfillment” of the original clinician order
	+ The EHR may generate all DiagnosticRequests at once or it may generate them in small batches (e.g. all orders for that day) or even just one at a time as they’re coming up
* EHR creates a Task for each child DiagnosticRequest seeking fulfillment from the lab.
	+ Tasks are typically only submitted close to the time fulfillment is sought, even if the child DiagnosticRequests are created all at once (as necessary to ensure time to collect specimens and perform other business processes)
* Standard fulfillment processes for each single DiagnosticRequest then continue
 |
| Add-on order | One order | Order placed to do extra tests on specimen already in progress | Existing specimen | Separate report from original order | Usually involves a call to the lab |
|  | * Clinician calls lab to see if they can add on an additional test (or set of tests) to a lab test already ordered
* Andrea will check w/ IHE process for doing this
* Lab chec
 |
| Scheduling |  |  |  |  |  |
|  |  |
|  |  |  |  |  |  |

Issues related to billing – may bill Medicare only on completion of all tests ordered on a panel

Example Panels:

1. Acute hepatitis
2. Basic Metabolic
3. Comprehensive Metabolic
4. Electrolyte
5. Hepatic Function
6. Lipid Screen
7. Obstetrics
8. Renal Function

Specimen attributes

Type

Container

Anticoagulant

Minimum Volume

Alternative specimens

Transport Temperature

Specimen Stability

Reject Criteria

Recommend attributes with order:

1. May be combined with other orders (Could this test be done on an existing specimen)
2. May substitute result from same test (on same day)
3. Partial reporting allowed
4. Specimen may be used for other testing

Culture, Aerobic Bacteria

CPT Code(s) 87070

Includes

If culture is positive, identification will be performed at an additional charge (CPT code(s): 87077 or 87140 or 87143 or 87147 or 87149). Antibiotic susceptibilities are only performed when appropriate (CPT code(s): 87181 or 87184 or 87185 or 87186).

Preferred Specimen(s)

Superficial wounds, skin, IV catheter tip. Collect specimen using culture swab transport device. Indicate source of specimen on both the requisition and specimen transport device. See Microbiology Specimen Collection section of the Specimen Collection Guide for Specific instructions.

For deep wounds requiring culture for both aerobic and anaerobic organisms order Culture, Wound, Deep (41327T) and submit specimen in Port-ACul vial tube. Submit exudate in in sterile leak-proof container or BD Vacutainer tube catalogue #366703. Do not use a barrier tube.

Minimum Volume one transport swab

Alternative Specimen(s)

Skin biopsy

Transport Container

Transport swab or sterile leak-proof container

 Transport Temperature

Room temperature

Specimen Stability

Room temperature: 48 hours

Refrigerated: 48 hours

Frozen: Unacceptable

Deliver to laboratory as soon as possible

Reject Criteria

Received frozen • Specimens submitted in formalin • Dry swabs • Expired transport media • Specimens >48 hours old

Methodology

Bacterial Culture, Aerobic

Includes routine isolation and identification procedures, antibiotic susceptibility testing when appropriate

Performing Laboratory

Setup Days

Monday-Sunday

Report Available

Negatives reported in 2 days

Clinical Significance

Aerobic bacteria cause a variety of human infections. Proper specimen collection and transport, media and incubation are important criteria for the recovery of aerobes. The primary aerobic bacterial agents of skin and tissue infections include S. aureus, P. aeruginosa, members of the enterobacteriaceae, and beta-hemolytic streptococci. The results of aerobic cultures assist the clinician with diagnosis and treatment of patients with bacterial infections. Proper interpretation of culture results is dependent on specimen source and known pathogenicity of the isolated organism.

LOINC®' Code(s)

NOTE: The codes listed in the table below are not orderable Test Codes.

Result

Code Result Name LOINC Code Component Name

60100253 CULTURE WOUND 634-6 Bacteria identified

60100254 CULTURE WOUND 634-6 Bacteria identified

60100255 CULTURE WOUND 634-6 Bacteria identified

60100256 CULTURE WOUND 634-6 Bacteria identified

60100258 CULTURE WOUND 634-6 Bacteria identified

60100259 CULTURE WOUND 634-6 Bacteria identified

60100260 CULTURE WOUND 634-6 Bacteria identified

60200062 SOURCE 31208-2 Specimen source

6320 CULTURE,WOUND 17915-0 Bacteria identified