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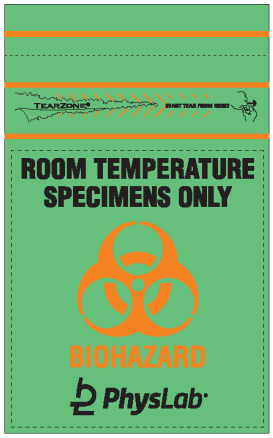
TECHNICAL BULLETIN

AUGUST 2016

NEW SPECIMEN TRANSPORT BAGS – EFFECTIVE AUGUST 1ST

Physicians Laboratory now has custom transport bags that indicate the specific temperature required for specimen storage and transport. Effective August 1st, clients should discard all clear bags and only utilize the temperature bags shown below:



Please discontinue the use of all clear plastic bags (as illustrated to the left). All unused clear bags should be destroyed. You do not need to return them to Physicians Laboratory. If you need to order new bags you can do so utilizing the following methods:

- Website (www.physlab.com)
- Contacting Client Service 1-800-642-1117
- Submit a Laboratory Supply Order Form
  - By Fax at 402-731-8653
  - By Mail
  - By Courier

MOLECULAR - HUMAN PAPILLOMA VIRUS (HPV) TESTING

Effective September 1, 2016 Human Papilloma Virus (HPV) High Risk testing and HPV Genotype testing will be performed on the Hologic Aptima (RNA) automated platform. The Aptima HPV 16 18/45 genotype assay can differentiate HPV 16 from HPV 18 and/or HPV 45, but does not differentiate between HPV 18 and HPV 45. HPV genotype 45 is fairly uncommon, identified in only 0.4% of women with normal cytology, yet data indicates that it is the third most common HPV genotype in invasive cancer. Testing for HPV genotype 45 is designed to help identify more women at risk for adenocarcinoma, with minimal impact to colposcopy rates. The Hologic Aptima (RNA) platform will replace the manual Hologic Cervista (DNA) test, currently being performed on HPV High Risk and HPV Genotype 16/18 testing.

HPV is responsible for more than 99% of all cervical cancers, which is one of the most common types of cancer affecting women throughout the world. The Aptima HPV assay identifies high-risk HPV infections by targeting E6/E7 mRNA. Studies show that targeting E6/E7 mRNA identifies the presence and activity of a high-risk HPV infection. The Aptima HPV assay represents the next generation in cervical cancer screening - allowing clinicians to deliver maximum benefits to patients, while minimizing potential harm. The Aptima HPV assay offers the same excellent sensitivity and improved specificity as compared to DNA-based tests.

Minimizes potential harm — improves specificity
Due to false-positives, cervical cancer screening can potentially result in the over-treatment of patients. To help minimize this potential harm, the Aptima HPV assay offers improved specificity, reducing the rate of false positive results. In the NILM (negative for intraepithelial lesion or malignancy) arm of the clinical trial to support FDA approval, the Aptima HPV assay showed 24% fewer false positive test results compared to DNA-based testing.[4]. With Aptima HPV, clinicians can more accurately target the right patients for coloposcopy.

mRNA and Cervical Disease
Unique features of the Aptima HPV assay include:

- The same excellent sensitivity
- Increased specificity compared to DNA-based tests
- FDA-approved for use with the ThinPrep Pap test
- Aligned with cervical cancer screening guidelines
- Only 1 mL of specimen required
- Internal control

Test #	Test Name
7613	HPV (Human Papilloma Virus) High Risk Screen (Without reflex)
7614	HPV (Human Papilloma Virus) High Risk Screen with Reflex to 16/18 Genotype

Acceptable Specimen Types:
Liquid Based Pap Vial – ThinPrep (FDA approved), SurePath (Validated by Physicians Laboratory)

References:
Hologic HPV Assay Package Insert - www.hologic.com

SPECIMEN LABELING REQUIREMENTS

Specimen identification is of the utmost importance in guaranteeing patient safety in the clinical laboratory setting. Proper patient identification followed by proper specimen labeling is an essential part of the testing process. To help prevent medical errors and safeguard patient safety the College of American Pathologists (CAP) and the Joint Commission require two patient identifiers on each specimen.

Acceptable specimen labels must include two (2) unique patient identifiers and must match exactly with the patient identification information on the accompanying order form, requisition, or identifying documents that are submitted with the specimen(s). Additionally, Anatomic pathology specimens must include the specimen source and date of collection.

It is important to note that the primary identifier must be the Patient's complete first and last name (spelled out – not abbreviated, nickname or alias). This information must match the requisition exactly. A first initial is not acceptable.

Appropriate second identifiers are as follows:

- Date of birth
- Medical record number
- Patient account number/chart number
- Requisition number

In an effort to clearly demonstrate the proper labeling of a sample, the requisition below was created on a fictitious patient. Examples of correct and incorrect labeling are also provided. Improper labeling will result in cancellation of testing. It is imperative that specimens are labeled with two identifiers that are identical to the information listed on the requisition.

PHYSICIANS LABORATORY SERVICES

LABORATORY REQUISITION

Order ID:

Phyisicians Laboratory Omaha: 402-731-4145 or 800-642-1117 4840 F Street 68117
Lincoln: 402-488-7710 7441 O Street Corporate Center Suite 100 68510

Patient Information:

Patient ID:

Patient Name: DOE, ROBERT
DOB: 01/01/1951
Patient Address:
Patient Home Phone:

Chart #: 123456
Sex: M

Client Information

Client Name: Physicians Laboratory Services, Inc.
Ordering Provider: Medical, Doctor
Provider Phone: (402) 555-1234

Client #: 0002
NPI: 1234567890
Entered By: Data, Entry

LABEL 1 LABELED CORRECTLY ACCEPTED	LABEL 2 LABELED INCORRECTLY MISSING 2ND IDENTIFIER REJECTED	LABEL 3 LABELED INCORRECTLY FIRST NAME ABBREVIATED REJECTED	LABEL 4 LABELED INCORRECTLY NICKNAME USED REJECTED
DOE, ROBERT 01/01/1951	DOE, ROBERT	DOE, R 01/01/1951	DOE, BOB 01/01/1951

AMMONIA TESTING

Ammonia is a highly unstable waste byproduct that will artificially increase after blood is drawn. In order to ensure accurate test results, strict criteria must be observed. Once drawn, ammonia is only stable for 30 minutes. The tube must be completely filled, kept unopened at all times and immediately placed on ice after the draw. The tube must then be centrifuged within 30 minutes. Once the tube has been spun, the plasma layer must be removed and frozen in a transport vial. If this cannot be accomplished in the time frame described, the test must be cancelled and the patient will have to be redrawn. Please follow the procedure below when ordering Ammonia testing:

- Have a green tube (lithium or sodium heparin) on hand.
- Place ice in a Styrofoam cup or directly into a biohazard bag.
- Fill out a requisition and make sure to document the exact collection time.
- Perform the draw by filling a green tube (lithium or sodium heparin) completely. Invert to mix. Do not open the tube until centrifuged.
- Label the tube with two identifiers. Place the tube immediately into the wet ice.
- As soon as possible (within 20 minutes of the draw), centrifuge the tube for 10 minutes.
- Upon completion, immediately remove the top plasma layer and transfer to a plastic transport vial and freeze. Be sure the transport vial is labeled with 2 identifiers and “Heparin plasma”.
- Package the blood and requisition in a blue frozen biohazard bag and give to the courier to be transported.

CHANGE TO SPECIMEN REQUIREMENTS FOR #9304 TESTOSTERONE FREE & TOTAL (FEMALES & CHILDREN)

Effective Immediately - When collecting samples for this test, you must separate serum from cells within 2 hours of collection. After separation from cells, the sample is stable for 24 hours room temperature, refrigerated 1 week, and frozen 6 months. If the sample is received unspun after 2 hours of collection, testing will be cancelled and the patient will need to be recollected.

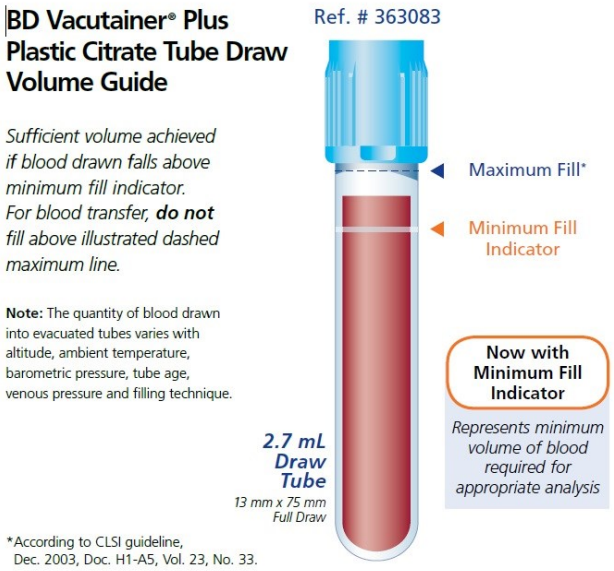
MODIFICATION TO REFERENCE RANGE

Effective June 20, 2016, the reference range for T3, Free changed from 2.5-3.9 to 2.7-4.4 pg/mL due to a formulary reagent change by the vendor. All reports properly indicate the corrected range.

PT, PTT, D-DIMER COLLECTION, STORAGE, AND STABILITY REMINDERS

Collection

Light blue top tubes must be filled completely in order to ensure accurate results. Sufficient volume is achieved if the blood drawn falls between the minimum and maximum fill line on the tube. If transferring blood from a syringe do not fill the tube above the illustrated dashed maximum line in the picture below. It is recommended a discard tube be used to establish blood flow prior to filling the light blue tube. Specimens that are not filled to the line on the tube or are overfilled will be cancelled.



Stability and Storage

After blood collection, there is progressive degradation of the labile coagulation factors V and VIII, leading to increased prolongation of the aPTT and PT. The allowable time interval between specimen collection and sample testing depends on the temperature encountered during transport and storage of the specimen. Allowable time intervals are as follows:

1. PT specimens, uncentrifuged, centrifuged with plasma remaining in the tube above the packed red cells, or as centrifuged plasma separated from the cells, should be kept at room temperature (18 to 24°C) and tested no longer than 24 hours from the time of specimen collection. PT specimens should not be refrigerated during storage or transport.
2. aPTT specimens that are uncentrifuged with plasma remaining in the tube above the packed red cells should be kept at room temperature (18 to 24°C) and tested no longer than 4 hours after the time of specimen collection.
3. aPTT specimens that are centrifuged and plasma separated from the cells should be kept 4 hours at room temperature (18 to 24°C) and tested no longer than 4 hours after the time of specimen collection.
4. If PT or aPTT testing cannot be performed within these times, platelet-poor plasma should be removed from the cells and frozen at -20°C for up to 2 weeks.
5. D-Dimer specimens are stable 4 hours refrigerated and frozen indefinitely. D-Dimer specimens must be tested no longer than 4 hours from the time of collection. If testing cannot be performed within this time, platelet-poor plasma should be removed from the cells and frozen at -20°C.
6. Specimens that exceed the appropriate stability requirements and/or are stored incorrectly will be cancelled.

References:

BD Vacutainer Plus Plastic Citrate Tube Draw Volume Guide. Ref #36083. http://education.bd.com/images/view.aspx?productId=1544
College of American Pathologists. Survey Coagulation, Limited CGL-A 2016.

CHANGES TO FECAL TESTING – EFFECTIVE IMMEDIATELY

#622	Fecal pH	Now sent to ARUP / CPT 83986
#623	Fecal Reducing Substances	Now sent to ARUP / CPT 84376
#619	Fecal RBC	Discontinued (Refer to Test #2620 Diagnostic Occult Blood)