Alverno Laboratories Client Information Manual

Account Number:

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ALVERNO LABORATORIES

IMPORTANT PHONE NUMBERS

MAIN LABORATORY

TOLL FREE: 1 (800) 937-5521

OR: (219) 989-3700

FAX: (219) 989-3900

CLIENT SERVICE

(219) 989-3700 → OPTION 0

FAX: (219) 989-3905

BILLING

(800) 937-2190

FAX: (815) 937-2191

LOGISTICS/COURIERS

(219) 989-3700

OPTION 3 FOR A PICK-UP

SUPPLIES

(219) 989-3882

FAX: (219) 989-3783

ALVERNO LABORATORIES

CONTACT INFORMATION

Your Alverno account number is _____

When calling the lab for any reason, please have your account number handy for identification purposes. This information will expedite our ability to access your account and answer your question in a professional and courteous manner.

Your Account representative is _____and can be reached at_____.
Our Client Service Department is available 24/7 at 219-989-3700 for support or questions.

- **Technical Consultation**

Our Pathologists are available for consultation with clients concerning the significance of test results, unusual cases, and technical matters. We also have a toxicologist available onsite for toxicology consultation. To reach one of these individuals, contact the Client Service department at 219-989-3700 and ask to speak to a pathologist or the toxicologist.

- **Other Consulting Services:**

Utilize our expertise and experience to help your business maximize efficiency and standardize your processes and procedures. Our quality team specializes in LEAN SIX SIGMA and can train your leaders to become better managers and strengthen their quality knowledge. Contact us for more information on consulting services from Alverno.

ALVERNO LABORATORIES

SPECIMEN COLLECTION, PREPARATION, AND HANDLING

• SPECIMEN REQUIREMENTS

The specimen requirement for each lab test is noted in the test description of our online collection manual which can easily be accessed through our website at https://alvernolabs.com/

This alphabetical listing of tests contains all testing available at Alverno Laboratories and a link to the reference laboratory for the most commonly ordered tests. For test information you may also call Alverno Client Service at (219) 989-3700 (Option 0).

• NOTIFICATION OF MINIMAL SAMPLE VOLUME

To maintain compliance with College of American Pathologists (CAP) guidelines, please refer to the optimal and minimal volume requirements when collecting samples. Alverno makes a concerted effort to up-date information as testing platforms change.

• BLOOD COLLECTION GUIDELINES

1. Verify all necessary collection requirements in the on-line collection manual, including diet restrictions, special timing, special test preparation, specimen type and volume, prior to beginning venipuncture procedure. Be sure that the necessary supplies are on hand for the venipuncture procedure. Venipuncture supplies are available from Alverno Laboratories. Contact Client Service if additional information is required.
2. Collection of blood sample is obtained by using the usual venipuncture technique. New gloves must be worn for each and every venipuncture procedure.
3. Properly identify patient by having patient state their full name and date of birth.
4. Apply a tourniquet to the patient's extended arm, approximately 3 to 4 inches above the venipuncture site and select the best vein. Swab the site with an alcohol prep pad (70% isopropyl alcohol swab).
5. Instruct patient to clench fist. The patient should not be allowed to pump their hand.
6. Enter the vein at the previously prepared puncture site at a 45^{o} angle. Stabilize the vein by holding the skin taught about 1 inch above and below the cleansed site. Point bevel of needle upward.
7. Engage the tube in the holder by pushing the tube completely into the holder, puncturing the stopper diaphragm. Watch the blood flow into the tube. Release the tourniquet as soon as blood begins to fill the tube. The tourniquet must be released within one minute of application; otherwise hemoconcentration will occur.
8. If multiple tubes are required, draw tubes using the CLSI recommended order of draw, see "Order of Draw" information sheet.
9. Mix all tubes containing additive immediately after drawing by gently inverting, according to the "Specimen Handling- Completing an Inversion" information sheet.
10. When the desired amount of blood has been drawn, verify the tourniquet was already released. Pull the tube off the needle, cover the puncture site with a dry gauze pad and quickly withdraw the needle from the vein. Apply pressure until bleeding has stopped.

BLOOD CULTURE COLLECTION

BACTEC Blood Culture Bottles:

- Recommended fill volume is 3.0 to 10.0 mL of blood.
- Optimum volume is 8.0 to 10.0 mL.
- Blue Top = aerobic bottles
- Pink Top = anaerobic bottles
- Yellow Blood Culture Collection Tubes – This tube is used exclusively for the collection of whole blood specimens for microbiological studies and must be received into the lab within 24 hours of collection for the blood to be transferred into the BACTEC bottles.
- Always draw blood culture bottles or tubes first if multiple tubes are drawn. Before the phlebotomy procedure, patients with a weight of ≥ 60 lbs. (27 kg) must have a discard tube drawn prior to the collection of the blood culture bottles. The cap of the discard tube MUST be physically cleaned with an alcohol prep pad and allowed to dry prior to beginning the phlebotomy procedure.

URINE COLLECTION

A random urine specimen optimally should be collected as “clean catch” in a sterile container. The specimen is then suitable for either urinalysis or urine culture. It is necessary to refrigerate every urine specimen prior to delivery to the lab. For a urine culture a sterile urine container containing a preservative should be used for urine storage. Alverno supplies sterile conical tubes for urinalysis specimens, grey-top urine culture tubes, and 24-hour urine collection containers. See the collection manual or call Client Services for collection information.

SPECIMEN REJECTION

Some common reasons the laboratory may reject a specimen are:

- Insufficient quantity for the test(s) ordered (QNS)
- Hemolyzed specimens
- Clotted anti-coagulant tubes or incompletely filled anti-coagulant tubes
- Incorrect tubes drawn for requested test
- Specimens not maintained at the appropriate temperature
- Mislabeled or unlabeled specimen tubes
- Specimens contaminated with an additive from another type of blood collection tube as a result of improper order of draw

The optimal amount of specimen should be sent unless there is difficulty in performing the specimen collection. Sometimes less sample will be acceptable. However, it is best to check the collection manual or contact the lab for minimum requirements whenever necessary.

LABELING

Laboratory regulating agencies require a minimum of two (2) patient identifiers as well as the collection date and time to be legibly printed on each primary specimen container. In compliance with laboratory regulations, we **will not** accept a specimen into our laboratory that is not properly labeled.

- **PROCESSING**

For some tests, the tube requires no extra processing. However, samples drawn for chemistry tests in serum separator tubes must have the serum separated from the cellular elements within 45 – 60 minutes after collection. This is accomplished by centrifuging the clotted blood sample. Alverno supplies clot activating, serum separator blood collection tubes which are ideal for the collection of serum. After centrifugation, the gel barrier provides a separation of the serum from the cellular elements without opening the primary tube. This labeled tube can then be submitted to Alverno without further handling.

If a serum is to be frozen immediately, allow the specimen to clot, centrifuge appropriately, and then pour the serum into a properly labeled plastic vial before freezing. DO NOT freeze glass blood collection tubes. Do not Freeze whole blood, unless specifically instructed to do so. Plastic vials are available from Alverno Laboratories.

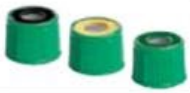
Always store the processed specimens appropriately prior to delivery to Alverno. If specimens cannot be placed in a refrigerator after collection, Alverno Laboratories suggests storage of the specimens in small cooler containing a coolant pack or a sealed bag of wet ice.

Please refer to the online collection manual for each test's storage requirement and any special handling requirements.

VACUETTE® Tube Guide

greiner bio-one

Venous Blood Collection Tubes

Cap Color	Additive	Number of Inversions	Testing Disciplines	Comments
	No Additive	5-10	Discard tube Transport/Storage Immunohematology Viral Markers	
	Sodium Citrate 3.2% (0.109 M) 3.8% (0.129 M)	4	Coagulation	If a winged blood collection set is used AND the coagulation specimen is drawn first, a discard tube is recommended to be drawn prior to this tube to ensure the proper anticoagulant-to-blood ratio.
	Clot Activator	5-10	Chemistry Immunochemistry Immunohematology Viral Markers	For complete clotting, 30 minutes minimum clotting time is required. Incomplete or delayed mixing may result in delayed clotting.
	Clot Activator w/Gel	5-10	Chemistry Immunochemistry TDMs	For complete clotting, 30 minutes minimum clotting time is required. Incomplete or delayed mixing may result in delayed clotting.
	Lithium Heparin Lithium Heparin w/Gel Sodium Heparin	5-10	Chemistry Immunochemistry	
	K_3 EDTA K_2 EDTA	8-10	Hematology Immunohematology Molecular Diagnostics Viral Markers	
	K_2 EDTA Gel	8-10	Molecular Diagnostics	
	Potassium Oxalate/ Sodium Fluoride	5-10	Glycolytic Inhibitor Glucose and Lactate	
	Sodium Heparin	5-10	Trace Elements	

Ring Indicator

yellow - Gel Separation | black - Standard Draw | green - Sodium Heparin | white - Pediatric Draw

see reverse for pediatric cap information

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888.286.3883 Phone | 800.726.0052 Fax
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VACUETTE® one step ahead

Order of Draw

CLSI Recommended*

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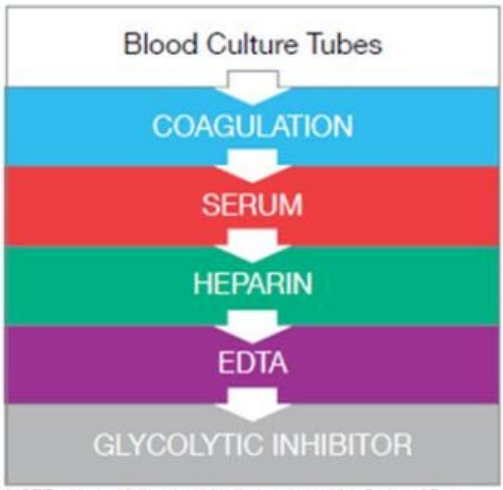

NOTE: Always follow your facility's protocol for Order of Draw

If a winged blood collection set is used, the first tube in the series will be underfilled. Therefore, if a coagulation specimen is drawn first, a discard tube (a no additive or coagulation tube) is recommended to be drawn prior to this tube to ensure the proper anticoagulant-to-blood ratio.

Tube Type	Recommended g-force relative centrifugal force (rcf)	Recommended Time (Minutes)
VACUETTE® Serum Tubes (Clot Activator, No Additive)	Minimum 1500 g	10
VACUETTE® Serum Clot Activator w/ Gel Tubes	1800 g	10
VACUETTE® K_2EDTA w/ Gel Tubes	1800 - 2200 g	10
VACUETTE® Plasma Tubes (Lithium Heparin, Sodium Heparin, PO/NaF)	2000 - 3000 g	15
VACUETTE® Lithium Heparin w/ Gel Tubes	1800 - 2200 g	10 - 15
VACUETTE® Coagulation Tubes (Sodium Citrate)		
Platelet tests (PRP)	150 g	5
Routine tests (PPP)	1500 - 2000 g	10
Preparation for deep freeze plasma (PFP)	2500 - 3000 g	20

*Reproduced with permission from CLSI. H21-A5, Collection, Transport and Processing of Blood Specimens for Testing Plasma-Based Coagulation Assays; Approved Guideline-Sixth Edition; H03-A6, Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture; Approved Standard - Sixth Edition. Copies of the current edition may be obtained from Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898, USA. Internet: www.clsi.org.

For further assistance: 888.286.3883 Phone | 800.726.0062 Fax | office@us.gbo.com | us.gbo.com

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Specimen Handling

Completing an Inversion

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To achieve the proper mix of additive and blood, each tube must be gently inverted as it is removed from the holder.

Importance of Mixing

- Insufficient or delayed mixing of serum tubes may result in delayed clotting
- Inadequate mixing of anticoagulant tubes may result in platelet clumping, clotting or incorrect test results

Cap Color	Tube Type	# of Inversions
Blue	Coagulation	4
Red	Serum	5 - 10
Green	Heparin	5 - 10
Lavender	EDTA	8 - 10
Grey	Glycolytic Inhibitor	5 - 10

One complete inversion

- Turn the filled tube upside down and return it to an upright position
- Repeat required number of times for each tube type

1 Inversion

For further assistance: 888.286.3883 Phone | 800.726.0052 Fax | office@us.gbo.com | us.gbo.com

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Preparing a Quality Sample

VACUETTE® Serum Separator Tubes

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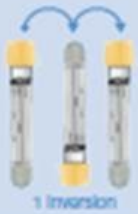
Gently invert the tube 5 - 10 times to allow the clot activator to mix with the sample.



Allow serum to clot (minimum of 30 minutes) in an upright position.

- Observe a complete clot before centrifuging sample.

Centrifuge no later than 2 hours after collection.

- Centrifuge at 1800g for **10 minutes** (or follow your facility's protocol).
- After barrier has formed separating serum from clot, transport to lab.

Collection Tips

for Coagulation Testing

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- **CLSI** recommends 3.2% (0.109M) of buffered citrate for coagulation assays.
- If a **winged blood collection set** is used, the first tube drawn in the series will be under-filled. Therefore, if a coagulation specimen is drawn first, a discard tube (a no additive or coagulation tube) is recommended to be drawn prior to this tube to ensure the proper anticoagulant-to-blood ratio.
- The following order of draw is recommended when drawing several tubes during a single venipuncture, and is used to avoid possible test result errors due to cross contamination from tube additives: (1) Blood Culture (2) Coagulation (3) Serum with or without gel (4) Heparin with or without gel (5) EDTA with or without gel and (6) Glycolytic Inhibitor. Always follow your facility's protocol for order of draw.
- Application of the **tourniquet** for vein selection should not exceed one minute of time. Following vein access, the tourniquet should be released as soon as possible following appropriate blood flow into the tube. If additional time is needed to locate the venipuncture site, remove the tourniquet for two minutes and reapply.
- For **hematocrit values** greater than 55%, adjust the volume of sodium citrate in the tube. Use the following formula to calculate the correct volume of sodium citrate used in the tube: $C = (1.85 \times 10^{-3})(100\text{-HCT})(V_{Blood})$; C = volume of sodium citrate required for that volume of blood; HCT = patient's hematocrit; V = volume of blood required in the blood collection tube and 1.85×10^{-3} is constant
- **Invert** each tube four times to ensure that the blood and anticoagulant are thoroughly mixed.
- Maintain the **9:1 blood to anticoagulant ratio** by filling the tube to the proper level or nominal fill line as indicated on the **VACUETTE®** tube label. Inadequate filling of the tube will decrease this ratio and may cause inaccurate test results.

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Coagulation Draw Volume Guide

Take the Guesswork Out of It

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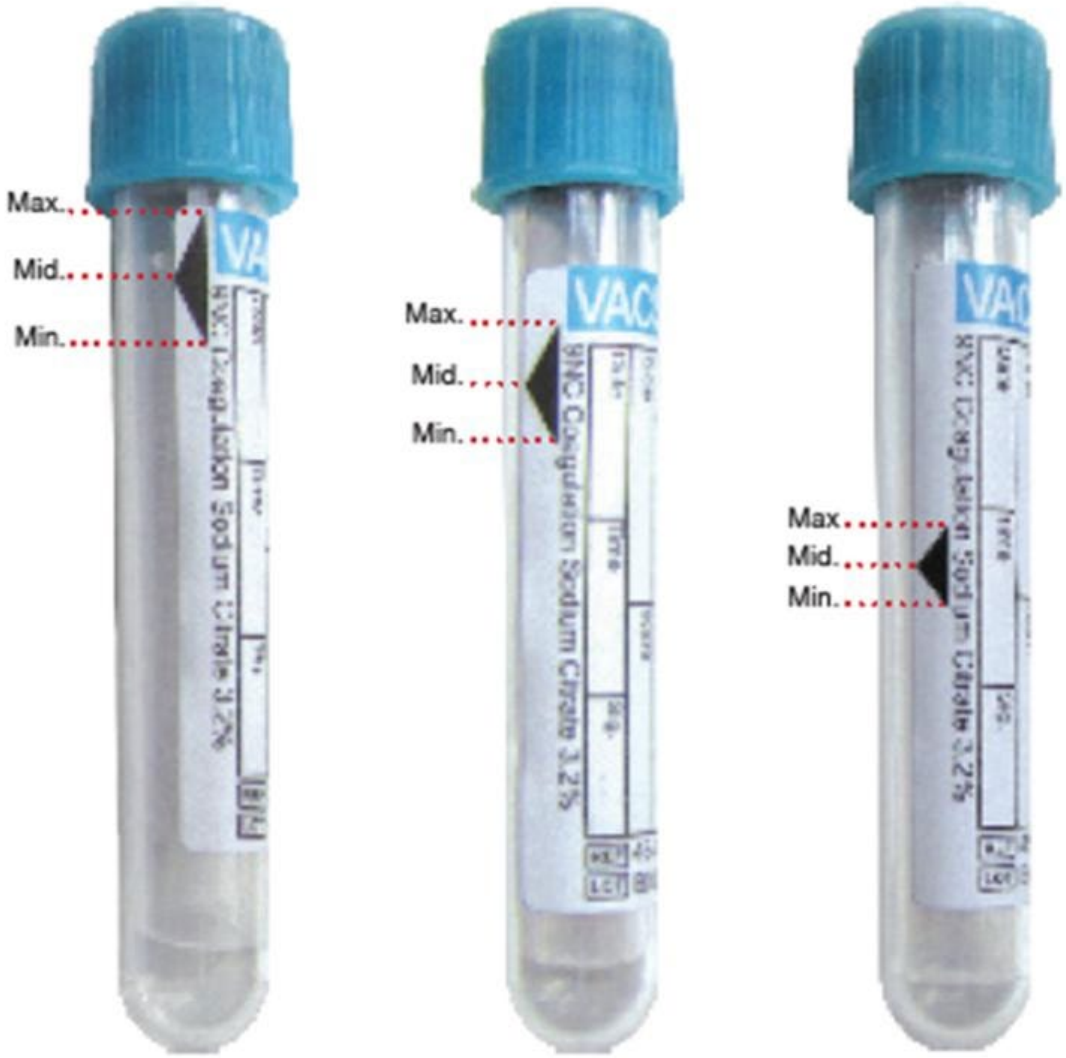
Ensure that the correct blood-to-additive ratio is met by checking the draw volume against the nominal fill mark on the tube or by holding tube up to this guide.



Sample within the range of the arrow represents 9:1 blood-to-additive ratio.

ALVERNO LABORATORIES

VACUETTE® Tube Conversion Guide

grelner blo-one

Venous Blood Collection Tubes

VACUETTE® Cap Type/Color	Additive	Number of Inversions	Testing Disciplines	Previous Cap Type/Color
	No-Additive	5-10	Discard tube Transport/Storage Immunohematology Viral Markers	
	Sodium Citrate* 3.2% (0.109 M) 3.8% (0.129 M)	4	Coagulation	
	Clot Activator**	5-10	Chemistry Immunochemistry Immunohematology Viral Markers	
	Clot Activator w/Gel**	5-10	Chemistry Immunochemistry TDMs	
	Lithium Heparin w/Gel	5-10	Chemistry Immunochemistry	
	Sodium Heparin Lithium Heparin	5-10	Chemistry Immunochemistry	
	K_2 EDTA K_3 EDTA	8-10	Hematology Immunohematology Molecular Diagnostics Viral Markers	
	K_2 EDTA Gel	8-10	Molecular Diagnostics	
	K_2EDTA	8-10	Hematology Immunohematology	
	Potassium Oxalate Sodium Fluoride	5-10	Glycolytic Inhibitor Glucose and Lactate	
	Sodium Heparin	5-10	Trace Elements	

RING INDICATOR

yellow - Gel Separation | black - Standard Draw | green - Sodium Heparin | white - Pediatric Draw

*If a winged blood collection set is used AND the coagulation specimen is drawn first, a discard tube is recommended to be drawn prior to this tube to ensure the proper anticoagulant-to-blood ratio.

**For complete clotting, 30 minutes minimum clotting time is required. Incomplete or delayed mixing may result in delayed clotting.

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VACUETTE® one step ahead

ALVERNO LABORATORIES

VACUETTE® Best Phlebotomy Practices

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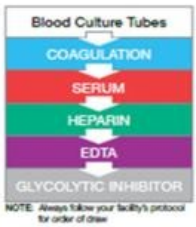
Steps		Action
Identify patient		• A minimum of two identifiers must be used. • Compare information to wristband and test requisition. • Resolve any discrepancies.
Prevent short filled tubes (quantity not sufficient QNS)		• Push tube forward so stopper is penetrated. • Hold tube in place using thumb on back of tube. • Keep tube in place until vacuum is exhausted. • Use discard tube if winged collection set is used and coagulation tube is drawn first.
Prevent hemolysis		• Tourniquet should be released no later than 1 minute after application. • Allow alcohol to dry for 15 – 20 seconds prior to vein puncture. • Choose appropriate equipment for venipuncture based on circumstance of the draw. • Mix tubes using recommended number of complete, gentle inversions. • Avoid drawing from Vascular Access Devices (VAD). If a VAD must be used, withdraw and discard approximately 5cc of fluid prior to drawing the sample. • Avoid excessive pulling force when using a syringe.
Prevent fibrin formation	 	• Fill tubes to level indicated on label. • Mix tubes with appropriate number of gentle inversions immediately following collection. • Allow serum tubes to sit 30 minutes prior to centrifugation. • Centrifuge tubes according to manufacturer's recommendations.
Follow order of draw		• Tubes should be collected in the correct order of draw as documented by CLSI H3-A6 or according to facility protocol.
Syringe draw		• If blood is collected in a syringe, a transfer device should be used to move the blood into evacuated tubes to minimize needlestick risk.
Label tubes		• Label tubes in presence of patient. • Reverify patient identification.

Place secondary labels along bottom edge of tube label, but far enough to the right so that additive and fill level marks are clearly visible.

MICROBIOLOGY

Alverno Laboratories offers a complete spectrum of diagnostic microbiology services. Please use sterile containers or tubes of transport medium, which will maintain viability without permitting overgrowth of non-pathogenic microorganisms. Please consult the on-line collection manual for specific mnemonics for accuracy when ordering. Collection containers and media may be obtained from our supply department. **Do not use expired sterile containers or media for transporting specimens.**

• GENERAL CONSIDERATIONS

1. Whenever possible, specimens should be obtained before antibiotics or other antimicrobial agents have been administered.
2. Collection containers should be closed securely, and precautions taken to prevent leaking of sample during transport. See microbiology collection guide.
3. Material should be collected where the suspected organism is most likely to be found and with as little external contamination as possible.
4. Specimen should be of a sufficient quantity to permit completion of all tests ordered.
5. Most clinical material can be held for several hours at room temperature before culturing if it cannot be processed immediately. This is particularly true with the following specimen types: sputum, and material on swabs taken from a variety of sources. Swabs should be maintained at room temperature until testing. DO NOT refrigerate stools (for enteric pathogen isolation) and body fluids such as CSF or blood.
6. All stools for Ova and Parasite exam require preservation in a fixative immediately after collection. Please order kits through Alverno Laboratories.

ALVERNO LABORATORIES

SPECIMEN COLLECTION GUIDE MICROBIOLOGY

Specimen collection instructions and guidelines may change. We recommend checking the collection manual for the most up-to-date collection information at www.AlvernoLabs.com

Reviewed April 2020

Reach us at 800-937-5521

ESWAB - CULTURES ONLY

Healthcare providers are encouraged to use the Eswab that best fits the specimen source and patient. Eswabs are interchangeable for all cultures in the section listed immediately below.

CANNOT BE USED FOR MOLECULAR OR RAPID KIT TESTING *EXCEPT* FOR MRSA BY PCR.

FLOCKED SWAB

ORDER#132433

Cultures:

Throat, Nasal, MRSA, Wound, Anaerobic, Group B Strep screens

GROUP A STREP ESWAB DUAL SWAB *FLOCKED + RAYON SWAB

ORDER# 171956

Rayon swab for in-office, rapid test.

If applicable, flocked swap to Alverno for reflex culture.

MINI-TIP

ORDER#132434

Cultures:

Ear, Eye, Gonorrhea
Genital cervical/urethral

FLEXIBLE MINI-TIP

ORDER# 132435

Cultures:

Nasopharyngeal - Sinus

PARA - PAK

CARY-BLAIR MEDIA

ORDER# 23205

Stool Culture - Vibrio Culture
Yersinia Culture - Shiga Toxin
E.coli 0157 Culture Testing

SAF FIXATIVE

ORDER# 11939

Ova and Parasite
O&P Screening

MINI TIP FLEXIBLE SWAB

ORDER# 9541

Influenza A and B testing by EIA method

URINE TUBES

NO ADDITIVES

ORDER# 353447

Legionella antigen by EIA Testing
Streptococcus pneumoniae antigen

BORIC ACID TUBE

ORDER# 26971

Urine Culture

ORDER# 25487

Use for transfer to tube

BD UTM

(Universal Transport Media)

ORDER# 111005

Rapid, qualitative detection of Influenza A Virus, Influenza B Virus, and Respiratory Syncytial Virus.

STERILE SCREW CAP CUP

(NO ADDITIVE)

ORDER# 15370

Sputum culture
Sterile body fluids
Tissue, hair, skin or nails
Stool for rotavirus testing by EIA

ALVERNO LABORATORIES

MOLECULAR DIAGNOSTICS

Polymerase Chain Reaction (PCR) testing is generally much faster and more sensitive than traditional culture methods for things like viruses, Neisseria gonorrhea, Chlamydia trachomatous, and MRSA. Here are some examples of common PCR tests and the required sample type. Refer to the collection manual for more detailed instructions and a comprehensive list of PCR testing availability.

- **SWABS SUBMITTED IN UNIVERSAL TRANSPORT MEDIA (UTM)**

  - Cytomegalovirus (CMV)
  - Herpes simplex virus 1 and 2 (HSV)
  - Varicella zoster virus (VZV)
  - Influenza and RSV, or Influenza only (INF A, INF B, RSV)
  - Mycoplasma pneumoniae
  - Respiratory Panel (includes 22 respiratory pathogens)
  - Bordetella pertussis (Includes parapertussis)

- **E-SWABS**

  - MRSA nasal screen
  - MRSA and Staph aureus presurgical nasal screen

- **ABBOTT MULTI-COLLECT SPECIMEN KIT**

  - Neisseria gonorrhea/chlamydia trachomatous
  - See instructions for collection of urine or swab samples. Note that urine samples have a minimum and maximum fill volume and must be within the min max fill lines indicated on the tubes.

- **BD MAX UVE COLLECTION KIT**

  - Vaginitis Panel (BV, TV, Candida sp. With krusei and glabrata callout)

ALVERNO LABORATORIES

SPECIMEN COLLECTION GUIDE MOLECULAR

Specimen collection instructions and guidelines may change. We recommend checking the collection manual for the most up-to-date collection information at www.AlvernoLabs.com

Reviewed April 2020

Reach us at 800-937-5521

THIN PREP PAP

ORDER# 144598

- HPV
- GC/Chlamydia

ABBOTT MULTI-COLLECT SPECIMEN COLLECTION KIT

ORDER# 176526

Intended for the collection and transportation of male and female, swab and urine specimens for the detection of Chlamydia trachomatis and Neisseria gonorrhoeae

BBL CULTURE SWAB LIQUID STUART

ORDER# 193216

OR E-SWAB

ORDER# 132433

- MRSA or MSSA by PCR

BD AFFIRM VAGINITIS PANEL

ORDER# 108401

- Gardnerella
- Trichomonas
- Candida sp.*

*does NOT identify the species of Candida yeast

BD Max Vaginitis Panel

ORDER# 181279

- Bacterial Vaginitis
- Trichomonas
- Candida species will be identified

E-SWAB

ORDER# 132433

- Group B Strep by PCR
- Vaginal/Rectal E-SWAB

BD UTM (Universal Transport Media)

ORDER# 111005

By PCR:

- Varicella zoster virus (VZV)
- Herpes virus 1&2
- Flu A / Flu B / RSV virus panel
- Flu A / Flu B virus panel
- Mycoplasma pneumoniae
- B pertussis and parapertussis
- Respiratory 21 Pathogen Panel
- SARS-CoV-2

STERILE SCREW CAP CUP (no additive)

ORDER# 153706

- Respiratory Wash/Aspirate
  - Flu A / Flu B / RSV panel
  - Flu A / Flu B panel
  - Respiratory 21 Pathogen Panel
  - B. pertussis and parapertussis
  - Mycoplasma pneumoniae
- HSV 1 and 2
  - Respiratory Wash / CSF
- Varicella Zoster Virus (VZV)
  - CSF
- C. diff by PCR
  - Stool
- Enteric Pathogen Panels
  - Stool (bacterial and parasitic)
- Norovirus
  - Stool
- CMV Qualitative by PCR:
  - CSF, Urine, Respiratory Wash

LAVENDER TOP TUBE: WHOLE BLOOD

ORDER# 193813

- Factor V Leiden Mutation by Real Time PCR
- Factor II Mutation by Real Time PCR
- Cystic Fibrosis screen: original tube only
- CD4/CD8 (T-Cell Subsets)
- Lymphocyte Subsets (T, B, and NK cells)
- Lymphoma/Leukemia Immunophenotyping by FlowCytometry
- Fetomaternal Bleed by FlowCytometry
- HLA B27 Detection by FlowCytometry

UROVYSION

ORDER# 135884

- For bladder cancer test collection use Urocyte Kit

PARA-PAK SAF FIXATIVE

ORDER# 11939

- Enteric Parasite Panel

PARA-PAK C&S CARY-BLAIR MEDIA

ORDER# 23205

- Gastrointestinal 22 Pathogen Panel
- Enteric Bacterial Panel
- Extended Enteric Bacterial Panel
- Norovirus

LAVENDER TOP TUBE: PLASMA*

ORDER# 193813

*Submit plasma in a transfer tube

- CMV Qualitative PCR
- CMV Quantitative PCR
- HCV Quantitative by PCR
- HIV Quantitative by PCR**
- HBV Quantitative By PCR

** requires plasma from 2 lav tubes

GREEN TOP TUBE: SODIUM HEPARIN

ORDER# 193842

- Hematological FISH testing for peripheral blood or bone marrow aspirate

SPECIMEN COLLECTION AND TRANSPORT GUIDE

For Abbott *m*ulti-Collect™ Specimen Collection Kit REF 9K12-03 9K12-04

Note: See package insert (9K12-03 or 9K12-04) for full instructions. Package insert instructions must be read carefully prior to use. Reliability of assay results cannot be guaranteed if there are any deviations from the instructions in the package insert.

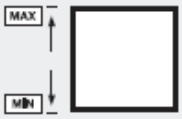
*m*ulti-Collect Urine Collection Procedure

PATIENT INSTRUCTIONS

1. The patient should not have urinated for at least one hour prior to sample collection.
2. Discard specimen collection swab; it is not required for urine specimen collection.
3. Using a urine specimen collection cup,* the patient should collect the first 20 to 30 mL of voided urine (the first part of the stream).

LABORATORY INSTRUCTIONS

4. Unscrew the transport tube cap, taking care not to spill the transport buffer within.
5. Handle the cap and tube carefully to avoid contamination, including the outside of the transport tube and cap. If necessary, change gloves.
6. Use the plastic transfer pipette to transfer urine from the collection cup into the transport tube until the liquid level in the tube falls within the clear fill window of the transport tube label or else a new specimen should be collected. Do not overfill. Slightly more than one full squeeze of the transfer pipette bulb may be required to transfer the necessary volume of urine specimen.



7. Recap the transport tube carefully. Ensure the cap seals tightly.
8. Label the transport tube with sample identification information, including date of collection using an adhesive label. Take care not to obscure the fill window on the transport tube.
9. Decontaminate and dispose of all specimens, reagents, and other potentially contaminated materials in accordance with local, state, and federal regulations.

URINE SPECIMEN AND SWAB SPECIMEN STORAGE AND TRANSPORT

10. After collection, transport and store transport tube at 2°C to 30°C for up to 14 days. If longer storage is needed, store at -10°C or colder for up to 90 days.

For domestic or international shipments, specimens should be packaged and labeled in compliance with applicable state, federal, and international regulations covering the transport of clinical, diagnostic, or biological specimens. It is recommended that each tube be placed in an individual, saleable bag prior to shipment.

* Not included in the multi-Collect™ Collection Kit

51-605161/R1

ALVERNO LABORATORIES

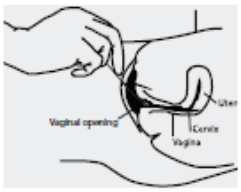
*m*ulti-Collect Swab Collection Procedure

CAUTION: Do NOT expose swab to Transport Buffer prior to collection.

1. Discard disposable transfer pipette; it is not required for swab specimen collection.

2. Remove the sterile swab from the wrapper, taking care not to touch swab tip or lay it down on any surface.

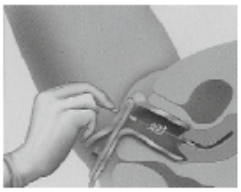
FEMALE SWAB SPECIMEN COLLECTION PROCEDURE



VAGINAL COLLECTION

3. Insert the white tip of the specimen collection swab about two inches (5 cm) into the opening of the vagina.*
4. Gently rotate the swab for 15 to 30 seconds against the sides of the vagina.
5. Withdraw the swab carefully. (continue with 6)

OR

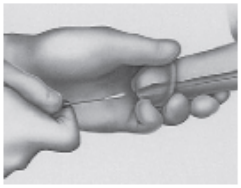


ENDOCERVICAL COLLECTION

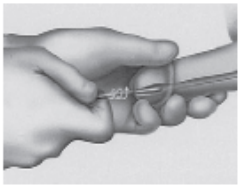
3. Insert the white tip of the specimen collection swab into the endocervix canal.
4. Gently rotate the swab for 15 to 30 seconds to ensure adequate sampling.
5. Withdraw the swab carefully. (continue with step 6)

MALE URETHRAL SWAB SPECIMEN COLLECTION

The patient should not have urinated for at least one hour prior to sample collection.



3. Insert the white tip of the specimen collection swab ¾ to 1½ inches (2 to 4 cm) into the urethra.



4. Gently rotate the swab for 2 to 3 seconds to ensure adequate sampling.
5. Withdraw the swab carefully. (continue with 6)

SPECIMEN HANDLING INSTRUCTIONS

6. Handle the cap and tube carefully to avoid contamination.
7. Unscrew the transport tube cap and immediately place the specimen collection swab into the transport tube so that the white tip is down.
8. Carefully break the swab at the scored line on the shaft; use care to avoid splashing of contents.
9. Recap the transport tube. Ensure the cap seals tightly.
10. Label the transport tube with sample identification information, including date of collection.

URINE SPECIMEN AND SWAB SPECIMEN STORAGE AND TRANSPORT

11. After collection, transport and store transport tube at 2 °C to 30 °C for up to 14 days. If longer storage is needed, store at –10 °C or below for up to 90 days.

    For domestic or international shipments, specimens should be packaged and labeled in compliance with applicable state, federal, and international regulations covering the transport of clinical, diagnostic, or biological specimens. It is recommended that each tube be placed in an individual, saleable bag prior to transport.

* Do not premoisten the swab with the transport buffer!

Abbott Molecular Inc.
1300 East Touhy Avenue
Des Plaines, IL 60018 USA

IVD

www.molecular.abbott

Abbott

51-605161/R1

ALVERNO LABORATORIES

ANATOMIC PATHOLOGY

- THIN PREP AND HPV COLLECTION

Utilize the PreservCyt® Solution for Thin Prep Collection provided by Alverno. Media is stable at room temperature until the expiration date printed on the vial. Once a specimen is placed in the vial, the vial is only good for 6 weeks from the collection date. Vials should be stored at room temperature.

WARNING!

- **DO NOT use a cytobrush on a pregnant patient.**
- **DO NOT use a cytobrush to sample the endometrium of any patient**.

Plastic Spatula

1. Obtain an adequate sampling from the ectocervix using a plastic spatula.
2. Rinse the spatula into the PreservCyt® Solution vial by swirling the spatula vigorously in the vial 10 times.
3. Discard the spatula.

Cytobrush device

1. Obtain an adequate sampling from the endocervix using an endocervical brush device. Insert the brush into the cervix until only the bottommost fibers are exposed. Slowly rotate ¼ or ½ turn in one direction. DO NOT OVER-ROTATE.
2. Rinse the brush in the PreservCyt® Solution vial by swirling the device in the vial 10 times while pushing against the vial wall. Swirl the brush vigorously to further release material.
3. Discard the brush.

Broom-like Device

1. Obtain an adequate sampling from the cervix using a broom-like device. Insert the central bristles of the broom into the endocervical canal deep enough to allow the shorter bristles to fully contact the ectocervix. Push gently and rotate the broom in a clockwise direction five times.
2. Rinse the broom into the PreservCyt® Solution vial by pushing the broom into the bottom of the vial 10 times, forcing the bristles apart. As a final step, swirl the broom vigorously to further release material.
3. Discard the collection device.

All Samples

1. Tighten the cap so that the torque line on the cap passes the torque line on the vial.
2. Record the patient's name, date of birth and collection date/time on the vial.
3. Record the patient information and medical history on the Anatomic Pathology requisition. Be sure all required information is provided, including test to be performed, ICD-10 codes and billing information.
4. Include signed ABN as needed.

5. Place the vial and requisition in a specimen bag for transport to the laboratory.

- CONVENTIONAL PAP SMEAR

*Alverno Laboratories provides the Pap kit, Spatula and Cytobrush

1. Using a spatula obtain an ectocervical scraping. Spread the material over half of slide nearest the frosted end. Spray the slide immediately with a fixative until saturated.
2. Then obtain material from the endocervix by gently inserting a cytobrush into the endocervical canal and slowly turning the cytobrush one full turn.
3. Remove the cytobrush and spread the material on the other half of the slide by rolling and twisting the cytobrush over the slide surface.

Cytobrush ONLY

1. Using the cytobrush, sample the vaginal fornix and portio. Then gently insert the cytobrush into the endocervical canal and slowly turning the cytobrush one full turn.
2. Remove the cytobrush and spread the material on the other half of the slide by rolling and twisting the cytobrush over the slide surface.
3. IMMEDIATELY spray fixative over the entire slide surface. Excess fixative is not harmful.

All Samples

1. IMMEDIATELY spray fixative over the entire slide surface. Excess fixative is not harmful.
2. With a pencil, print the patient's last name and first initial on the frosted end of the glass slide.
3. Allow the slide to dry completely. Place the slide in folder, close and secure the lid.
4. Discard collection device. NEVER reuse collection devices.
5. Complete the patient information and medical history on the Anatomic Pathology requisition form.
6. Place the slide and requisition in a specimen bag for transport to the laboratory.

Cytology Non-Gyn Specimens

*See Collection manual for individual tests and specimen requirements

- TISSUE SPECIMEN

Alverno provides tissue Kits. Kit is stable at room temperature until the expiration date printed on the vial. Once a specimen is placed in the vial, the specimen is good until the expiration date of the vial it is contained in. Vials should be stored at room temperature.

- SPECIMEN HANDLING

1. Place specimen in buffered 10% formalin fixative screw-capped container.
2. A separate container must be used for each "source" of tissue.

3. Assure that the container has been properly labeled with at least two patient identifiers, including the patient's full name and one other identifier such as the patient's birthdate.
4. Care should be taken to assure that the specimen is not leaking.
5. Record the patient information and medical history on the Anatomic Pathology requisition form.
6. Specimen is to be placed in a specimen transport bag with the requisition in the outside pouch.

• GENERAL CONSIDERATIONS WHEN HANDLING 10% FORMALIN

Persons should wear chemical safety goggles, chemical resistant gloves and protective clothing when handling formalin. Formalin is a potential carcinogen. If formalin comes into contact with eyes or mucous membranes, flush with water for 15 minutes. If formalin is ingested, consult with a physician immediately to determine appropriate treatment. In case of a spill, absorb on paper, vermiculite, etc. To dispose of waste, consult federal, state and local regulations. A copy of the manufacturer SDS for the formalin must be available onsite. If a copy of the SDS sheet is required, please contact the Client Service Department.

• ADDITIONAL INFORMATION FOR THE USE OF THE HOLOGIC® THIN PREP PAP TEST

ALVERNO LABORATORIES

Dear Colleague,

On occasion, Hologic personnel are asked to provide information concerning the use of lubricants when collecting a Pap sample with the ThinPrep® Pap test. As part of Hologic's continuing education for clinicians and laboratorians, this bulletin addresses the proper preparation of the cervix for an adequate Pap sample collection pertaining to the ThinPrep Pap test and the use of lubricants on the speculum. Steps taken by the clinician, from patient education to improved sampling technique, may ensure that the sample collected maximizes the potential of the ThinPrep Pap test.[1,2]

Patient Education:
Women should be counseled to refrain from intercourse, douching, using tampons or intravaginal medication for at least 48 hours before the examination to decrease the possibility that the number of exfoliated cells will be diminished or obscured by personal lubricants or spermicides.[1,2] In addition, the patient should avoid scheduling her appointment during heavy menstrual bleeding.[1] If you would like patient education materials for your office, please contact your Hologic representative.

Sample Collection Options for Lubricating the Speculum:

1. Lukewarm Water: For a patient without physical or physiologic reasons for needing lubricant, lukewarm water may be used to warm and lubricate the speculum. This protocol poses the least risk to the quality of the Pap sample collected.[1,3] Professional organizations including ACOG and CLSI recognize that excessive use of lubricant may contaminate or obscure the Pap sample.

2. Lubricant Gels: If lubricant must be used due to patient discomfort or other circumstances, it should be used sparingly and applied ***only*** to the exterior sides of the speculum blades, ***avoiding contact with the tip of the speculum*** (see pictures below).[1-4] When a lubricant is used sparingly and appropriately it poses little risk to the quality of the Pap sample. However, when a lubricant is used in excess, it can adversely affect the Pap sample.

Hologic evaluated a variety of popular lubricants and found those containing carbomer or Carbopol polymers (thickening agents) interfere with the ThinPrep Pap test when found in the sample vial.[5] Hologic recognizes the varying availability of different types of lubricants and recommends that, if used, any lubricant should be applied sparingly as described below.

ALVERNO LABORATORIES

Appropriate Use of Lubricant for ThinPrep Pap Sample Collection

Apply a dime-sized amount of lubricant gel.

Apply only to exterior sides of the speculum, avoiding the tip.

Should you have further questions regarding this topic, please refer to the CLSI guidelines or contact the Hologic Technical Support Department at 1-800-442-9892, option 6.

Sincerely,

Philipp Mueller

Sr. Director Medical and Scientific Affairs

References: 1. Davey DD, et al. Cervical Cytology Specimen Adequacy: Patient Management Guidelines and Optimizing Specimen Collection. *J Low Genit Tract Dis*. 2008;12(2):71-81. doi: 10.1097/LGT.0b013e3181585b9b 2. Amies AE, et al. The Effect of Vaginal Speculum Lubrication on the Rate of Unsatisfactory Cervical Cytology Diagnosis. *Obstet Gynecol*. 2002;100(5, Pt 1):889-892. 3. CLSI. Cervicovaginal Cytology Based on the Papanicolaou Technique; Approved Guideline – Third Edition (GP15-A3). Wayne, PA: Clinical Laboratory Standards Institute; 2008. 4. ACOG. Cervical Cancer Screening and Prevention. Practice Bulletin No. 168. *Obstet Gynecol*. 2016;128(4):e111-30. doi: 10.1097/AOG.0000000000001708 5. Hologic, Inc. Internal study. Data on file.

250 Campus Drive, Marlborough, MA 01752 USA | +1.508.263.2900 | Hologic.com

ALVERNO LABORATORIES

HOLOGIC®

ThinPrep® Pap Test Lubricant Compatibility List

The use of lubricants with the ThinPrep Pap test is not recommended. However, if a lubricant is necessary the following lubricant brands are validated by Hologic, Inc. for use with the ThinPrep Pap test when used as instructed.[1]*

	Lubricant	Manufacturer	Contains Carbomer?
Preferred†	Pap Test Lubricating Jelly	Aseptic Control Products	No
	Surgilube Surgical Lubricant	HR Pharmaceuticals	No
	CerviLube Lubricant	Sion Brands	No

	Lubricant	Manufacturer
Not Approved‡	Aquagel Lubricating Gel	Parker Laboratories, Inc.
	Astroglide (Physician Formula)	BioFilm, Inc.
	Astroglide (Personal Formula)	BioFilm, Inc.
	HR Lubricating Jelly	HR Pharmaceuticals, Inc.
	Lubricating Gel	Henry Schein
	Lubricating Jelly	McKesson
	MediChoice Lubricating Jelly	Owens & Minor
	PDI Lubricating Jelly I and II	PDI Healthcare
	PSS Select (also known as Triad)	PSS World Medical, Inc.
	Rite Aid Pharmacy Lubricating Gel	Rite Aid Corp.
	Allegiance	Medline Industries, Inc. (formerly Triad/H&P Industries)
	Aplicare Sterile Lubricating Jelly (also known as Operand Lubricating Jelly)	Aplicare Inc./Clorox Professional
	Aqua Lube Personal Lubricant	Mayer Laboratories
	DynaLube Lubricating Jelly	Dynarex Corporation
	E-Z Lubricating Jelly	Chester Packaging
	IMCO Lubricating Jelly	Medline Industries, Inc. (formerly Triad/H&P Industries)
	Lubricating Jelly	DUKAL Corporation
	Lubri-Gel	Sheffield Pharmaceuticals
	Maxilube Personal Lubricant	Mission Pharmacal
	NovaPlus	Medline Industries, Inc. (formerly Triad/H&P Industries)
	Pro Advantage Lubricating Jelly	National Distribution & Contracting, Inc.
	ReliaMed Lubricating Jelly	ReliaMed

*The use of lubricants (including personal lubricants) should be avoided prior to specimen collection. Lubricants can adhere to the filter membrane and may cause poor cell transfer to the slide. If its use is unavoidable, the lubricant should be used in minimum amounts.

†Validated: Lubricants have multiple lots run through periodic testing to ensure compatibility.

‡Not approved: Lubricants have either been tested and deemed incompatible or excluded from testing because they contain carbomer.

Reference: 1. ThinPrep 2000 System Operator's Manual. MAN-02585-001. Marlborough, MA: Hologic, Inc.; 2017

ThinPrep® PAP TEST

ALVERNO LABORATORIES

Dear Colleague:

Hologic strives to provide you with processes and products to help you deliver targeted care to your patients. As part of this commitment, if lubricant must be used due to patient discomfort or other circumstances we recommend the use of Surgilube lubricant from HR Pharmaceuticals, Pap Test Lubricating Jelly from Aseptic Control Products and Sion CerviLube lubricant from Sion Brands — three carbomer-free lubricants that have all been validated by Hologic for use with the ThinPrep® Pap test.[1*]

All three of these lubricants passed stringent testing by Hologic and meet established quality parameters without impacting ThinPrep Pap test results. **We only advise using carbomer-free products because lubricants containing the synthetic polymers, regardless of their quality, can affect test results and should not be used with ThinPrep Pap testing.**

Ultimately, healthcare providers are responsible for providing counsel to patients to refrain from using over-the-counter lubricants and vaginal medications 48 hours prior to the collection of any Pap sample. All healthcare providers should follow the guidelines for Pap collection as indicated in CLSI and ACOG guidelines.[2,3]

Purchasing details for the validated lubricants

- **Surgilube** lubricant is available for purchase through numerous medical distributors and GPOs listed on their website Surgilube.com. It is available in several packaging types:

MFR #	Item Description	Volume	Packaging
281020536	Screw/Fez Cap (Metal Tube)	4.25oz (120.49gm)	12 ea/bx – 6 bx/cs (72)
281020502	Screw/Fez Cap (Metal Tube)	2oz (56.7gm)	12 ea/bx – 12 bx/cs (144)
281020555	Metal Tube – Elongated Tip	5gm	48 ea/bx – 3 bx/cn – 4 cn/cs
281020537	Flip Top Cap (Laminated tube)	4.25oz (120.49gm)	12 ea/bx – 6 bx/cs (72)
281020512	Flip Top Cap (Laminated tube)	2oz (56.7gm)	12 ea/bx – 12 bx/cs (144)
281020543	Foilpac® (Foil laminated film)	3gm	144 ea/bx – 12 bx/cs (1728)
281020545	Foilpac® (Foil laminated film)	5gm	144 ea/bx – 6 bx/cs (864)

Part numbers, packaging configurations and pricing are set by HR Pharmaceuticals, Inc. and are subject to change without notice.

- **Pap Test Lubricating Jelly** is available in several packaging options directly through its manufacturer or from various medical distributors. Manufacturer location:

  Aseptic Control Products, Inc., 3831 Industrial Ave. Unit D, Rolling Meadows, IL. 60008
  P: (800) 448-0131 P: (847) 342-1729 F: (847) 342-1809
  info@acpmedicalinc.com
  www.acpmedicalinc.com

Description	ACP Item #	Packaging
Pap Test Lubricating Jelly, 3-gram packet, non-sterile	024-PKT/BX 024-PKT/CS	144/box 1,728/case
Pap Test Lubricating Jelly, 4-oz flip top tube, non-sterile	024-PKT/BX 024-PKT/CS	12/box 72/case

- **Sion CerviLube** lubricant is available in several packaging options directly through its manufacturer or from various medical distributors. Please contact their customer service for more information at the following:

  Vanessa Palafox
  832-761-3912
  vanessa@sionbrands.com

Description	Packaging
CerviLube 3-gram CAR/PAR Free	144/box 144x12/case
CerviLube 4-oz CAR/PAR free	6/box 6x12/case

*The Pap Test Lubricating Jelly (PN#s 024-PKT, 024-PKT-BX, 024-4OZ, 024-4OZ-BX) tested by Hologic on August 21, 2013, Surgilube lubricant (PN#s 281020536, 281020502, 281020555, 281020537, 281020512, 281020543, 281020545) tested by Hologic on March 3, 2016, and Sion CeviLube lubricant (3 g and 4 oz) tested on April 22, 2019, are the only lubricants validated by Hologic. If the vendor modifies the raw materials and/or the formulation is modified, approval by Hologic and this document shall be null and void.

References: 1. ThinPrep 2000 System Operator's Manual. MAN-02585-001. Marlborough, MA: Hologic, Inc.; 2017. 2. CLSI. Cervicovaginal Cytology Based on the Papanicolaou Technique; Approved Guideline – Third Edition (GP15-A3). Wayne, PA: Clinical Laboratory Standards Institute; 2008. 3. ACOG. Cervical Cancer Screening and Prevention. Practice Bulletin No. 168. *Obstet Gynecol.* 2016;128(4):e111-30. doi: 10.1097/AOG.0000000000001708

BILLING REQUIREMENTS AND STANDARDS

Alverno Laboratories offers the client the following billing options:

Medicare and/or Medicaid Patient Billing: Under CMS statute, a laboratory must bill Medicare and Medicaid directly for clinical laboratory services. Physicians may not bill the Medicare program for laboratory tests they do not perform. The client must provide the following demographic information in the "Billing Information" box on the Alverno test requisition:

- MEDICARE AND/OR MEDICAID PATIENT BILLING

Under CMS statute, a laboratory must bill Medicare and Medicaid directly for clinical laboratory services. Physicians may not bill the Medicare program for laboratory tests they do not perform. The client must provide the following demographic information in the "Billing Information" box on the Alverno test requisition:

- Patient name
- Date of birth
- Address
- Medicare number or Railroad Medicare or Medicare Replacement policy numbers
- Medicaid number/Eligibility form
- All applicable diagnosis codes relating to the testing being ordered

- PRIVATE PATIENT BILLING (NON-MEDICARE OR MEDICAID)

If requested by the client, Alverno will bill the patient directly. The client must provide the following demographic information in the "Billing Information" box on the Alverno Test Requisition:

- Guarantor: patient name or responsible party
- Date of birth
- Relationship to Insured
- Address
- Insurance plan including Full Name, Claim Address, Phone number, Policy and Group numbers as applicable
- All applicable diagnosis codes relating to the testing being ordered

Diagnosis information is preferred in ICD-10 format when insurance billing is requested.

- CLIENT ACCOUNT BILLING

If requested, Alverno will bill non-Medicare / Medicaid patient tests to the client on an itemized monthly statement. A list by date of service, patient name, CPT code, test(s) ordered, and charges will be printed and issued to the client's account. The test

requisition should be marked as "Bill Client Account".

Payment terms are defined in the client's contract. Any patient discrepancies must be reported to Alverno in writing. Adjustments will appear on subsequent invoices.

- CPT CODING

As a service to our clients, Alverno has provided the American Medical Association's (AMA) Current Procedural Terminology (CPT) codes for test listed on our test menu. It is the responsibility of the client to research and verify the accuracy of the CPT codes that they use for billing purposes.

CPT codes are listed in an effort to provide some guidance to use for billing; however, these are our interpretations of CPT coding requirements and may not be correct. It is the clients' responsibility to determine correct CPT codes to use for billing. Therefore, Alverno assumes no responsibility for billing errors due to reliance on CPT codes we provide for your reference.

- MEDICAL NECESSITY

When ordering tests for which Medicare reimbursement will be sought, physicians or authorized individuals should only order tests that are medically necessary for the diagnosis and treatment of a patient. The Office of the Inspector General takes the position that a physician who orders medically unnecessary testing may be subject to civil penalties.

Medicare carriers have been instructed by the Centers for Medicare & Medicaid Services (CMS) to implement policies that ensure the medical necessity of certain services rendered to Medicare beneficiaries. These are called National Coverage Determinations (NCD). Although national policies have been created, each carrier has the authority to choose those procedures for which a Local Coverage Determination (LCD) can be created. Therefore, the procedures subject to LCD may vary among Medicare carrier jurisdictions.

Once an NCD or LCD is in place for a test, the carrier requires medical necessity documentation in order to determine coverage. A carrier will deny coverage for a limited coverage test when it is submitted without specific diagnosis information, which supports the medical necessity for the testing. Each carrier publishes the NCD's and LCD's with covered ICD-10 codes. Alverno Clinical Laboratory in turn publishes an annual packet of NCD's and LCD's for clients. Updates are issued throughout the year.

Whenever you order a test, which is subject to an NCD or LCD, an ICD-10 code is required on Alverno's test request form. The ICD-10 code should indicate the medical necessity that you, in your judgment, believe is appropriate for the test. Please provide the ICD-10 code that most accurately describes the patient's condition. Do not choose a code merely to secure claim payment. ICD-10 codes must be provided in valid format, including 4th and 5th digit specificity when required. The ICD-10 code that you provide to Alverno must appear in the patient's medical records in order to support the necessity of the testing in the event of a post-payment review.

ALVERNO LABORATORIES

- MEDICARE WAIVER (ADVANCED BENEFICIARY NOTICE OF NON-COVERAGE)

Medicare frequently denies payment for certain laboratory tests based on the assumption that the test(s) is (are) not medically necessary. For these tests, Medicare has published a limited number of diagnoses that are "medically necessary" according to Medicare guidelines nationally, as well as for that specific state. If a diagnosis does not meet Medicare guidelines at the time of service, the caregiver must notify the patient in advance that Medicare is unlikely to pay for the lab test and they will be financially responsible for the test.

Advanced Beneficiary Notice of non-coverage forms (ABN) are provided to all clients in English and Spanish versions. The patient must complete and sign the ABN to agree to testing and financial responsibility.

- **A patient refusing to sign the waiver is the same as refusing the test. Document this on the ABN form. The testing will not be performed.**
- **Insurance carriers may also implement clinical testing guidelines. Anthem BC has established guidelines. If applicable, complete the Anthem BC ABN.**

The Medicare Beneficiary has three options. The patient may select only one of the three options and check that box.

1. **If the patient does agree to be responsible for payment for these tests if Medicare denies payment, he/she should mark the Option 1 box.**
2. **If the patient wants the tests listed above, but does not want Medicare billed, he/she should mark Option 2 box.**
3. **If the patient does not agree to be responsible for payment for these tests, he/she should mark the Option 3 box. In this case no specimen will be drawn for these tests and the tests will not be performed.**

The patient, or authorized representative, must sign and date the ABN form. If any information is not completed, the ABN form is considered invalid and the physician office will take financial responsibility. Instructions for the Completion of the Medicare Advanced Beneficiary Notice of Non-coverage (ABN).

The Advanced Beneficiary Notice of Non-coverage ABN must be completed anytime that there is a suspicion that Medicare will not pay for the test based on medical necessity or frequency. Form CMS-R-131 is required. Alverno's name, address, and contact phone number are required in the header.

- Please print the patient's name as it appears on their Medicare card.
- Please enter an identification number for the beneficiary (example: chart number). The Medicare number will no longer be used on the form.
- In the first blank field, fill in the default term for the services – refer to underlined wording: "Medicare does not pay for everything, even some care that you or your health care provider have good reason to think you need. We expect Medicare may not pay for the lab tests below".
- In filling in the column under Laboratory Tests, enter the lab test name of all testing that are the subject of the notice.

- In the Reason Medicare May Not Pay field: list the reason applicable across from the appropriate test.
- Possible reasons are:
    - “Medicare does not pay for these tests for your condition”.
    - “Medicare does not pay for these tests as often as this (denied as too frequent)”.
    - “Medicare does not pay for experimental or research use tests”.
- In the Estimated Cost field: The patient (beneficiary) may be responsible for paying for this (these) test(s) if Medicare denies payment. Enter in a good faith estimate of the cost of each test listed on the ABN notice
- The Medicare Beneficiary (patient) must be given a copy of the signed Advanced Beneficiary Notice. You may accomplish this either by photocopying the signed ABN or by inserting a carbon paper between two ABN forms. Please give the patient the legible copy of the original. The original ABN should be returned to the laboratory along with the requisition. You may keep an additional copy for charting purposes.

ALVERNO LABORATORIES

TESTING INFORMATION AND REPORTING GUIDELINES

TEST ORDERING

Alverno Laboratories will provide our clients with customized test requisitions. All customized requisitions will include the Client ID number, ward designation, location address and phone number and additional pertinent information relative to client. Requisitions are available at no cost to our client and will be supplied as needed. Please allow 3 to 5 business days to receive a replenishment order. Requisition orders will be delivered by courier. If you have a scheduled courier after normal business* hours, please remember that we will not leave requisitions in your lock box. We ask that if you use more than 500 requisitions in a month that you reorder in lots of no more than 250 each time. At your request, we would be happy to schedule an automatic replenishment of requisitions for your facility. This will save your staff the time and trouble of reordering when your supply begins to run low.

Our Clinical requisition lists the most commonly ordered blood serum and plasma tests performed at Alverno, in addition you will find sections for Approved test panels, with a component listing on the back of the requisition, Therapeutic drug testing, Blood Bank and Routine Cultures, and Drugs of Abuse – non-DOT screening. Tests not listed on the requisition can be manually written in the area at the bottom of the form reserved for additional tests. If OB / AFP screening is ordered, you are required to complete the patient history section of the requisition.

Our Pathology / Cytology requisitions are available for PAP testing and will be preprinted with your facility information. The required information relative to patient history is listed so accurate results will be reported. Please be sure to mark as necessary to prevent any delay in receiving results.

Your Alverno representative will be happy to go over the forms with you and answer any questions you may have.

TEST REQUISITION

- Complete an Alverno Test Requisition for every patient encounter.
- Client number will be preprinted on the requisition. If not preprinted, please write client number on the requisition.
- Add any special “phone”; “copy”; or “fax” requests. Only use this field if immediate notification is needed of if delivery is outside your normal delivery service.
- Customized area for each client.
- Ordering Physician – The ordering physician signature is required by EMS.
- Please fill out the patient information section completely and legibly. Include patient name, SS#, date of birth, sex, date, and time of collection, collected by and fasting state.
- There are six bar-coded tube labels which may be placed on your samples. This is an additional patient identifier.
- Patient insurance information. Please fill out this section as completely and legibly as possible. If the patient, patient’s insurance, or Medicare/Medicaid is to be billed, complete the responsible party demographics and insurance information. Preferred attachments – a

photocopy of the patients' insurance card (front and back) may be attached to the first page of the requisition – please refer to the coordination page for further information.

- Test Section: The test section is divided into the following sections:
  - Medicare Approved Panels
  - Therapeutic Drugs
  - OB AFP Screen and required history for completion of the test
  - Blood-Serum-Plasma tests – General laboratory tests listed in alphabetical order.
  - Blood Bank Microbiology Tests: Please include specific site information. Example: for a Wound Culture include the specific site that the culture was collected from (i.e., Right Hand).
  - Urine/Feces tests
  - Other tests
  - Check the test(s) to be performed.
  - National Coverage Medical Necessity tests are indicated on the requisition by a (⍰). For further information and clarification, please refer to the Medical Necessity information in the Billing section.
- ICD-10 diagnosis code must be provided for each test requested. Note: Medicare guidelines state that a diagnosis must be provided for each and every laboratory test ordered, in order to document medical necessity. As well, every insurance company requires ICD-10 code when billing. Alverno Laboratories, LLC requests that the physician provide an ICD-10 diagnosis code to document Medical Necessity for each test/panel ordered for each patient encounter. Please document all ICD-10 diagnostic codes in the ICD-10 Diagnosis Code field of the requisition.
- The reverse side of the first page of the requisition includes:
- Panel Components: This is a list of all the Medicare approved panels with their components.
- The reverse side of the second page of the requisition includes services that will automatically be interpreted by a Pathologist.
- After the requisition is completed, the first and second pages should be separated:
  - The first page (along with attached photocopy of insurance information) should be sent along with the patient or the specimen to the laboratory for processing. Place specimen(s) in an Alverno specimen transport bag, along with the requisition. Process and store specimens appropriately until delivery to Alverno.
  - The second page should be kept by the physician's office to be included in the patient's chart as documentation of laboratory work performed.
- Is this a Medicare patient?
  - Check the diagnosis for medical necessity
  - Does the ABN need a signature?

• TEST ADDITIONS

At the client's request, Alverno will arrange to perform additional testing if a sufficient specimen volume remains after the initial tests are completed. Specimen type, optimal storage stability, and specimen quality must first be considered.

In addition, Federal regulations require that laboratory maintain on file, written authorization for all laboratory testing. Accordingly, we will submit a verbal phone order form to the physician which is to be

signed and returned promptly to the Client Service department either by fax to (219) 989-3905 or by courier with the next specimen pick-up.

- TEST CANCELS

Tests may be canceled without charge at any time before the test is performed and reported. Please notify Alverno Client Service as soon as possible whenever it becomes necessary to cancel a test.

- REPEAT EXAMS

Alverno Clinical Laboratories guarantees the quality of every test that is performed in our laboratories. If the attending physician would like for a test value to be rechecked, we would be happy to comply. Please notify Alverno Client Service of your concern.

For most assays, the specimen is retained in the laboratory for 5 days after initial testing is completed. At your request, the specimen will be retrieved, optimal storage and specimen quality will be checked, and the test will be repeated at no charge.

- RETENTION OF SAMPLES

After testing is completed, the samples are kept stored and refrigerated and then discarded.

- Urine containers – discarded after 7 days
- Stools – discarded after 7 days
- Swabs – discarded after 7 days
- Lavender-top tubes discarded after – 5 days
- Original tubes that have been spun discarded after – 5 days
-

Samples that must be retained for longer than 5 days are kept frozen. The retention times for all samples will vary and are based on such criteria as:

- State and federal regulations
- Test manufacturer's recommendations
- Deterioration of the analyte
- CAP requirements and NCCLS guidelines
- Acute/convalescent testing requirements
- Pending litigation

Appropriateness of testing is ultimately a technical decision and is made by the technical staff using test-specific criteria. Alverno's sample storage policy assures availability of adequate and reliable specimens.

- TURNAROUND TIME

Most routine laboratory tests are performed daily. Generally, test results will be available on the same day or evening that the specimens were collected and/or delivered to Alverno Clinical Laboratories.

Expected turnaround for tests that are not performed daily are noted in the on-line collection manual. If testing is to be delayed for any reason, Alverno Laboratories, LLC will immediately inform the client of the delay and /or make the appropriate arrangements for backup testing.

REFERENCE TESTING

Alverno maintains status as the primary core laboratory for routine and specialized testing of specimens. Our Healthcare Purchasing Group may recommend reference labs for off-site laboratory testing, subject to the approval of Alverno Laboratory's Medical Director. Criteria for selection of other reference laboratories may include:

- Certification by CLIA, CAP, AABB and/or other recognized agencies.
- Acceptable turnaround time for tests results
- Courier availability, packaging requirement and specimen transport
- Timely and accurate alert notification
- Customer Service and Consultation
- Quality and Reliability
- Contract / Cost

Our arrangements with referral laboratories are reviewed periodically to ensure that:

- All requirements including pre-examination and post examination procedures are adequately defined, documented and understood.
- The referral laboratory continues to meet the requirements and there is no conflict of interest.

REPORTING RESULTS

Laboratory test results can be delivered in several ways, speak to your account representative for the most appropriate option.

- Direct interface to your EMR
- Auto fax upon completion of testing
- Auto fax at specific time(s)
- Printed, delivered, or mailed to the client's location

Whenever possible, tests are completed, and reports generated within 24 hours.

Markedly abnormal test results that appear on the Alert Value list will be phoned to the client or physician within 30 minutes of test completion and verification. Documentation of this notification will be stated on the printed patient report. Alert notification is a quality monitor that is reported to the Alverno Quality board and is required for CAP certification. Every alert value received by the Client Service Department is reviewed to ensure that it was phoned and read back by the nurse or physician within 30 minutes. All outliers are reviewed through our quality process to determine the root cause of the failure.

If a test cannot be performed as ordered, Alverno will make notification of the test cancellation to the client. Written notice of the cancellation, including the reason for the cancellation, will be forwarded to the client for charting in the patient's clinical record.

• REFERENCE RANGES

Alverno establishes its own reference ranges for analytes whenever possible. For some procedures, it is necessary to use ranges suggested by the reagent manufacturer or reported in literature. Age and gender specific reference ranges are provided when available or established. We encourage your input in developing our reference ranges.

Reference ranges are listed on patient test reports.

LOGISTICS, COURIER SERVICE, AND LOCK BOX INFORMATION

- SPECIMEN TRANSPORT

Safety/Compliance:

OSHA and DOT guidelines mandate that specimens of blood or other potentially infectious materials shall be placed in a container which prevents leakage during collection, handling, storage, transport or shipping. All specimens transported to Alverno Clinical Laboratories must be placed in an Alverno biohazard specimen transport bag. Requisitions should be folded and placed in the bag and then place the corresponding MedSpeed Bar Code on the outside of the bag for scanning. Please refer to the **online collection manual** for specimen storage requirements.

The couriers are trained in handling your specimens and transport to our lab in the proper transportation containers to maintain specimen integrity. Please refer to the "**MEDSPEED COURIER SCAN BARCODING FOR TRANSPORT" guide**.

Scheduled Needs:

Please refer to "**MEDSPEED LOCK BOX USER GUIDE"** for helpful information, page 35.

On-Demand Needs:

Please place job in the MedSpeed via portal*or call to submit request for specimen pickup. If calling, you will be given a confirmation number upon calling for a pickup, please keep for your records.

Holiday Schedule:

Alverno recognizes six major holidays and the courier routing is on a Sunday schedule for these holidays. If you have a Sunday scheduled pickup it will occur on the holiday. If you do not, please place job in the MedSpeed via portal *or call to prearrange courier service on the following days:

- New Year's Day
- Memorial Day
- Independence Day
- Labor Day
- Thanksgiving Day
- Christmas Day

*For access to the MedSpeed portal- email: Medspeed-Hammond@medspeed.com

Request, access to MedSpeed portal and Alverno Database.

- MEDSPEED COURIER SCAN BARCODING FOR TRANSPORT

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Specimen Packaging

To ensure proper and safe handling of specimens, please ensure adherence to the following:

1. BAG

- Place specimens in the specimen bags.
- OSHA regulations require 3 barriers between the specimens and the external environment: these consist of the test tube, the specimen bag, and the lockbox, cooler, or other container.
- Specimens should be packaged ***individually***:
  - Place "**1 Patient" per specimen bag**. Multiple specimens for the same patient may be combined in the same specimen bag.
- Ensure that specimen bags are properly identified as room temperature, refrigerated and frozen.

2. BARCODE

- MedSpeed barcode labels are provided in duplicate sets:
  - Place the barcode label on the outside of the specimen bag. Keep the right portion of the label for your records (this label contains the barcode reference number).

Sample MedSpeed Duplicate Bar Code Label

*Please use the Alverno supply request form to order more labels

3. PICKUP LOCATION

- Bring specimen to pickup location (refer to Alverno Lockbox Guide).
- Place the specimen bags, complete with the barcode labels, in the appropriate container.

Questions or comments?

- MEDSPEED COURIER SCAN BARCODING FOR TRANSPORT

ALVERNO LABORATORIES

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Lockbox User Guide

Lockboxes are useful tools that offer flexibility and efficiency for our clients. Please use this guide to support specimen viability.

- Lockboxes should be placed in the most sheltered area of your building.
  - Please keep safety in mind. Choose a well-lit area, away from extreme elements
- On a daily basis, remove all lockbox receipts, mail, and supplies placed in your lockbox by the courier.
- Mark all bagged specimens according to specimen type.
  - Refrigerated-All individually bagged specimens are to be barcoded and clearly marked "Refrigerated"
  - Room Temp-All individually bagged specimens are to be barcoded and clearly marked "Room Temp"
  - Only place frozen specimens in lockbox if using approved Alverno lockbox Frozen Pack or call MedSpeed to arrange a special pick-up
- Put specimens in your lockbox as close to your designated courier pickup time as possible
- To prevent the possibility of a "Missed Pickup"
  - Be familiar with your designated courier pickup time
  - If you will not have specimens ready for your designated courier pickup time, you will need to call MedSpeed Dispatch to set up an on-demand pickup
- **EXTREME WEATHER**
  - Do not allow specimens to be in your lockbox for long periods of time
  - If your office is closing early due to extreme weather, please contact MedSpeed Dispatch and/or Alverno Client Services
  - If the temperature is ≤ 5°, MedSpeed will ensure all scheduled outside lockbox pick-ups are complete within 2 hours of the earliest pick-up time
    - For on-demand orders during extreme weather, please request 2-hour pick-up window from when specimens will be placed in the lockbox

MedSpeed Operations 800.937.5521 Option 3, Option 1
Alverno Client Services 800.937.5521 Option 2

MedSpeed Lock Box Guide- kept in Policy STAT for reference 9/24/2015

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THE UNABLE TO COMPLETE SERVICE NOTICE

WHAT IT IS AND WHY IT IS CRITICAL TO SPECIMEN VIABILITY

As an ISO-certified, technology-enhanced healthcare transportation solutions provider, MedSpeed's goal is to provide you, our valued partner, with a high-quality, safe, dependable healthcare transportation operation. Reducing errors, of any kind, is an extremely high priority. To that end, MedSpeed has implemented the Unable to Complete Service process, described below, to help ensure that we do not miss any valuable pick-ups.

HOW IT WORKS

Occasionally, when attempting to complete a pickup or delivery, our LSRs will be unable to access the stop location or will not find any items in the designated pickup locations. Since healthcare is a dynamic industry, we understand that there may in fact be days when there is nothing to be collected. However, as a precaution, our LSRs take the following steps to double check with your team or, if the office is already closed, notify you that we were there.

1. If no items are found at the designated location during a scheduled pickup, our LSR will double check with your team to verify that there are no pickups that day.
2. If the designated location is inaccessible or there are no items found during an on-demand pickup, the LSR will call our central dispatch team, who will follow up with your personnel who called in the request and resolve the discrepancy.
3. If our team is unable to reach yours to verify that there are no items for pickup or delivery, the LSR will leave an "Unable to Complete Service" form. The purpose of this form is to notify your team that our LSR visited your location and did not complete the pickup or drop off because the location was not accessible, or no items were found. For lockbox pickups, this form will be left sticking out of the box so your team can easily see it.
4. In any case, the LSR will record that no items were picked up or dropped off into his or her handheld scanner device for reporting purposes.

WHAT TO DO IF YOUR LOCATION RECIEVES A NOTICE

The purpose of the Unable to Complete Service notice is to communicate to you that we did not find any specimens or other patient critical items at the designated pickup location or were not able to access the designated stop location and will not be back until the next scheduled visit.

- If you do not have any items for pickup, you do not need to take any further action.

- If you have a specimen or critical item for pickup and see a note on your lockbox, call the MedSpeed On-Demand team immediately at 000.000.0000 to arrange for a MedSpeed LSR to come to your location. To ensure specimen viability, it is critical for you to call the MedSpeed team as soon as possible. There may be an additional charge for a second pick-up, so it is important to make sure items are put in the designated location before the regularly schedule pickup.

CLIENT SERVICES

CLIENT SERVICE

(219) 989-3700

FAX: (219) 989-3905

Alverno Laboratories is proud to offer our clients personal, professional services. Our Client Service department has consistently been rated in the 98th percentile for Customer Satisfaction and Professionalism by our customers.

We encourage you to contact our Client Service Representatives with any questions or concerns that may arise. Client Services is available to serve you 24 hours a day, 365 days a year, even on Holidays.

Our Client Service representatives are always willing and able to help assist you. Please contact Client Services for things like:

- Result queries
- Patient demographics
- Test add on
- Test cancellation
- Missed specimen pick-ups
- Arrange an on-call pickup
- Order test requisitions
- Place an order for supplies
- Verify receipt of specimen

ORDERING SUPPLIES

SUPPLIES

(219) 989-3882

FAX: (219) 989-3783

Alverno Clinical Laboratories, LLC provides collection supplies to clients for specific use in collection and submission of specimens to our laboratories. In compliance with Federal regulations, Alverno may provide clients only those blood collection supplies that do not have multiple uses, are directly related to the collection of specimens and in amounts proportionate to the specimens received from the client. Alverno cannot provide supplies if the testing is being performed by the client or at another laboratory.

Supplies and containers for laboratory services are provided at no additional charge to our clients. These include all blood collection tubes, needles, needle holders, containers, preservative solutions and special collection containers and devices. Supply request forms can be accessed online at:

https://my.ssfhs.org/aclsupplyrequest/

or from the Alverno homepage in the provider section. Please reference your Alverno client account number on all orders.

Supplies can be ordered:

1. Online: Use the form referenced above to place an order. Enter an email address to receive a confirmation receipt when your order is completed.
2. By phone: Call the Alverno Client Service department and place your order using the Alverno product number(s). Orders are taken weekdays 8:30 a.m. until 5 p.m.

Please allow 3 – 5 days for orders to be processed and delivered. Supplies will be delivered by your courier. Supplies are not delivered on weekends unless special arrangements have been made in advance.

ALVERNO LABORATORIES

REFLEX TESTING LIST

The Pathology Council of Alverno Laboratories has determined that follow-up testing and/or confirmation of the following tests is medically necessary in order to provide appropriate patient care. See your client account representative for the most up-to-date list of reflex testing.