

Cleveland Clinic Laboratories

Technical Update • March 2015

Cleveland Clinic Laboratories is dedicated to keeping you updated and informed about recent testing changes. That's why we are happy to provide this technical update on a monthly basis.

Recently changed tests are bolded, and could include revisions to methodology, reference range, days performed or CPT code. For your convenience, tests are listed alphabetically and the order and billing codes are provided.

If you wish to compare the new information with previous test information, refer to the Test Directory, which can be accessed at clevelandcliniclabs.com.

Deleted tests and new tests are listed separately. Please update your database as necessary. For additional detail, contact Client Services at 216.444.5755 or 800.628.6816 or via email at clientservices@ccf.org.

Test Update Page #	Summary of Changes by Test Name	Order Code	Billing Code	Name Change	New Test	Test Discontinued	Special Information	Specimen Requirement	Component Change	Methodology	Days Performed/Reported	Reference Range	CPT	Fee
9	ACTA2 Gene Sequencing													
9	Adenovirus Antibodies													
3	Adenovirus DFA													
3	AFB Culture Only													
8	Allergen, Perch IgE													
3	APC Resistance													
9	Arbovirus Antibodies, IgG and IgM, Serum													
3	Beta hCG Quant Tumor Marker													
9	BK Virus Quantitation, Urine													
9	Bromide, Blood													
3	Catecholamines, Fractionated, Plasma													
9	Cortisol, Saliva													
3, 9	DHEA													
3	DHEA-S													
3	Diphenhydramine													
3	Diphenhydramine, Urine													
4	Estrone													
4, 9	Fructosamine													
4	Helicobacter pylori Antigen, Stool													
4	Hepatitis Delta Virus Antigen													
4	Herpes Simplex Ag Detection													
9	Hexosaminidase A & Total, WBC													

Test Update Page #	Summary of Changes by Test Name	Order Code	Billing Code	Name Change	New Test	Test Discontinued	Special Information	Specimen Requirement	Component Change	Methodology	Reference Range	Days Performed/Reported	CPT	Fee
5	HIV-1 Western Blot													
9	HLA B5701													
5	Hydrocodone & Metabolites													
9	Hyperoxaluria, Urine													
9	Inhibin A and B, Tumor Markers, Serum													
8	Legionella Pneumophila, Antibody													
5	Liver Kidney Microsome IgG Autoabs													
9	L/S Ratio													
9	Mycoplasma Genitalium by PCR													
5	Myeloid Malignancies Mutation Panel by Next Generation Sequencing													
9	Narcolepsy Evaluation													
5, 9	Norovirus Group 1 and 2 Detection by PCR													
6	Opiate Confirmation, Urine													
6, 9	Pregnenolone													
6	Quantitative Pain Panel, Urine													
6	Rickettsia rickettsii IgG & IgM Abs													
6	Rufinamide													
7	T3 Uptake													
9	Tay-Sachs (Hexosaminidase)													
9	Transthyretin DNA Sequencing													
7	Varicella-Zoster DFA													
9	VWD Type 2A, 2B, 2M Exon 28 Sequence Analysis													

*Please note: Cleveland Clinic Laboratories is now using BD Vacutainer® Collection Products for the following tests; Urine Culture (URCUL), Urinalysis Only (UA), and Urinalysis with Microscopic (UAWMIC).

Use of preservative has several benefits and is considered best practice.

1. Ensures most accurate results under routine transport conditions. Specimens can be maintained at room temperature for up to 48 hours.
2. Improves safety and sample recollection due to leaking cups.
3. Can improve CAUTI (catheter associated UTI) rates and decrease unnecessary therapy due to false positive results.
4. Meets regulatory requirements for specimen integrity.

Test Changes

Test Name	Order Code	Billing Code	Change	Effective Date
Adenovirus DFA	DADNO	77003	Days Performed: 7 Days a Week	2/24/2015
AFB Culture Only	AFCO	90507	Billing Code: 90507	2/18/2015
APC Resistance	APC	79045	Clinical Information: Evaluation of hypercoagulable states and thrombic disease. Factor V Leiden PCR assay can be used to confirm APC resistance due to factor V Leiden. Ratios less than 2.07 suggest APC - resistance. High heparin concentrations (> 1 U/mL) and direct thrombin inhibitor drugs may interfere with test results. Lupus anticoagulant and other coagulation inhibitors may also interfere with test results. Causes of APC resistance other than abnormalities of factor V may not be detected by this assay as all factors except factor V are replaced in the assay. Reference Range: 0-99 Years: >2.06 Ratio	3/2/2015
Beta hCG Quant Tumor Marker	BHCG	87712	Specimen Requirements: 1.0 mL Serum - SST (Gold - 0.2 mL minimum); Refrigerated. Remove serum from cells within 2 hours of collection. Alternate - 1.0 mL Plasma - EDTA (Lavender - 0.2 mL minimum); Refrigerated. Remove plasma from cells within 2 hours of collection. OR - 1.0 mL Plasma - sodium or lithium heparin (Green - 0.2 mL minimum); Refrigerated. Remove plasma from cells within 2 hours of collection. OR - 1.0 mL Serum - no additive (Red - 0.2 mL minimum); Refrigerated. Remove serum from cells within 2 hours of collection. Methodology: Immunochemiluminometric Assay (ICMA) Days Performed: Monday-Saturday Reported: 3-6 Days Reference Range: Male: 0-99 Years: <4 IU/L Female: 0-99 Years: <6 IU/L Stability: Frozen: After separation from cells: 3 Months Refrigerated: After separation from cells: 1 Week Ambient: Unstable	5/12/2015
Catecholamines, Fractionated, Plasma	PLCAT	41000	Special Information: Overnight fasting is required. Patients should be relaxed in either a supine or upright position before blood is drawn. States of anxiety and stress can cause fluctuations in the catecholamine levels. Patient should avoid alcohol, coffee, tea, tobacco and strenuous exercise prior to collection.	4/9/2015
DHEA	DHEA	75487	Specimen Requirements: 1.0 mL Serum - SST (Gold - 0.5 mL minimum); Refrigerated. Collect between 6-10 am. Separate serum from cells within 2 hours of collection. Alternate - 1.0 mL Plasma - sodium or lithium heparin (Green - 0.5 mL minimum); Refrigerated. Collect between 6-10 am. Separate plasma from cells within 2 hours of collection. Days Performed: Monday, Wednesday, Friday Reported: 3-6 Days Stability: Frozen: After separation from cells: 3 Weeks Refrigerated: After separation from cells: 1 Week Ambient: After separation from cells: Unacceptable	5/12/2015
DHEA-S	DHEAS	75410	Stability: Frozen: 2 Months Refrigerated: 2 Days Ambient: 4 Hours	5/5/2015
Diphenhydramine	DIPHEN	87797	Stability: Frozen: 24 Months Refrigerated: 1 Month Ambient: 1 Month	5/4/2015
Diphenhydramine, Urine	UDIPHN	87818	Stability: Frozen: 24 Months Refrigerated: 1 Month Ambient: 1 Month	5/4/2015

Test Changes (Cont.)

Test Name	Order Code	Billing Code	Change	Effective Date
Estrone	EST	75641	<p>Specimen Requirements: 0.5 mL Serum - SST (Gold - 0.3 mL minimum); Refrigerated. Centrifuge. Serum must be separated from gel within 24 hours of collection.</p> <p><i>Alternate</i> - 0.5 mL Serum - no additive (Red - 0.3 mL minimum); Refrigerated.</p> <p>Methodology: Tandem Mass Spectrometry (TMS)</p> <p>Days Performed: Tuesday, Thursday, Saturday</p> <p>Reported: 4-6 Days</p> <p>Reference Range:</p> <p>MALE: 7-9 Years: <7 pg/mL 10-12 Years: <11 pg/mL 13-15 Years: 1-30 pg/mL 16-17 Years: 1-32 pg/mL 18-99 Years: 9-36 pg/mL Tanner Stage I: <7 pg/mL Tanner Stage II: <11 pg/mL Tanner Stage III: 1-31 pg/mL Tanner Stage IV-V: 2-30 pg/mL</p> <p>FEMALE: 7-9 Years: <20 pg/mL 10-12 Years: 1-40 pg/mL 13-15 Years: 8-105 pg/mL 16-17 Years: 4-133 pg/mL 18-99 Years: Premenopausal: Early Follicular < 150 pg/mL 18-99 Years: Premenopausal: Late Follicular 100-250 pg/mL 18-99 Years: Premenopausal: Luteal < 200 pg/mL 18-99 Years: Postmenopausal: 3-32 pg/mL Tanner Stage I: <27 pg/mL Tanner Stage II: 1-39 pg/mL Tanner Stage III: 8-117 pg/mL Tanner Stage IV-V: 4-109 pg/mL</p> <p>Stability: Frozen: 1 Month Refrigerated: 1 Week Ambient: 4 Days</p>	5/12/2015
Fructosamine	FRUCTO	76672	<p>Specimen Requirements: 1.0 mL Serum - SST (Gold - 0.2 mL minimum); Refrigerated.</p> <p><i>Alternate</i> - 1.0 mL Plasma - lithium heparin (Green - 0.2 mL minimum); Refrigerated.</p> <p>Special Information: Hemolysis may cause falsely elevated results.</p> <p>Methodology: Colorimetry</p> <p>Days Performed: Monday-Saturday</p> <p>Reported: 3-4 Days</p> <p>Reference Range: 180-280 umol/L</p>	5/12/2015
Helicobacter pylori Antigen, Stool	SHPYLR	82624	<p>Specimen Requirements: 1.0 g Stool - sterile container; Frozen. Collect fresh unpreserved stool in a clean, leak proof, wax-free plastic container and freeze ASAP.</p> <p>Special Information: Antimicrobials, proton pump inhibitors, and bismuth preparations are known to suppress H. pylori. Ingestion of these less than two weeks prior to testing may give a false negative result.</p> <p>Days Performed: Monday-Saturday</p> <p>Reported: 3-5 Days</p> <p>Reference Range: Not Detected</p> <p>Stability: Frozen: Indefinite Refrigerated: 3 Days Ambient: Unacceptable</p>	5/12/2015
Hepatitis Delta Virus Antigen	HDVAG	77113	<p>Stability: Frozen: 3 Months Refrigerated: 1 Week Ambient: Unacceptable</p>	2/2/2015
Herpes Simplex Ag Detection	DHSV	77055	Days Performed: 7 Days a Week	2/24/2015

Test Changes (Cont.)

Test Name	Order Code	Billing Code	Change	Effective Date
HIV-1 Western Blot	HIV1CO	75778	<p>Specimen Requirements: 2.0 mL Serum - SST (Gold - 0.5 mL minimum); Refrigerated. Separate serum or plasma from cells ASAP or within 2 hours of collection.</p> <p>Alternate - 1.0 mL Plasma - sodium citrate (Light blue - 0.5 mL minimum); Refrigerated. Separate serum or plasma from cells ASAP or within 2 hours of collection.</p> <p>OR - 1.0 mL Plasma - sodium or lithium heparin (Green - 0.5 mL minimum); Refrigerated. Separate serum or plasma from cells ASAP or within 2 hours of collection.</p> <p>OR - 1.0 mL Plasma - EDTA (Lavender - 0.5 mL minimum); Refrigerated. Separate serum or plasma from cells ASAP or within 2 hours of collection.</p> <p>Special Information: Order this assay only when a specimen is repeatedly reactive for HIV 1 or HIV 1-2 antibodies.</p> <p>Methodology: Western Blot (WB)</p> <p>Clinical Information: This assay should not be used for blood donor screening, associated re-entry protocols, or for screening Human Cell, Tissues, and Cellular and Tissue-Based Products (HCT/P).</p> <p>Days Performed: Sunday, Tuesday-Saturday</p> <p>Reported: 2-4 Days</p> <p>Component: Test build may need to be modified.</p> <p>Stability: Frozen: Indefinitely (Avoid repeated freeze/thaw cycles) Refrigerated: 1 Week Ambient: Up to 1 week is acceptable, but not preferred.</p>	5/5/2015
Hydrocodone & Metabolites	HYDSER	88457	<p>Test Name: Previously Hydrocodone, Serum</p> <p>Includes: Dihydrocodeine, unconjugated, Hydromorphone, unconjugated, Hydrocodone, unconjugated</p> <p>Specimen Requirements: 5.0 mL Serum - no additive (Red); Refrigerated. Do not use serum separator tubes. Please collect 2 specimen tubes to ensure adequate volume.</p> <p>Methodology: Gas Chromatography Mass Spectrometry (GCMS)</p> <p>Days Performed: Tuesday-Saturday</p> <p>Reported: 6-9 Days</p> <p>Reference Range: Hydrocodone, unconjugated: 10-40 ng/mL Hydromorphone, unconjugated: 10-30 ng/mL Dihydrocodeine, unconjugated: Not Established</p> <p>Stability: Frozen: 180 Days Refrigerated: 14 Days Ambient: 3 Days</p> <p>CPT: 80361x1</p>	3/16/2015
Liver Kidney Microsome IgG Autoabs	LKM	76521	<p>Specimen Requirements: 0.5 mL Serum - SST (Gold - 0.1 mL minimum); Refrigerated.</p> <p>Methodology: Immunofixation Assay (IFA)</p> <p>Days Performed: Monday-Saturday</p> <p>Reported: 3-4 Days</p> <p>Reference Range: 0-99 Years: < 1:20 titer</p> <p>Stability: Frozen: 3 Months Refrigerated: 3 Days Ambient: Unacceptable</p>	5/12/2015
Myeloid Malignancies Mutation Panel by Next Generation Sequencing	MYENG5	90462	CPT: 81455	2/5/2015
Norovirus Group 1 and 2 Detection by PCR	NORPCR	89448	<p>Days Performed: Tuesday, Friday</p> <p>Reported: 3-6 Days</p>	3/23/2015

Test Changes (Cont.)

Test Name	Order Code	Billing Code	Change	Effective Date
Opiate Confirmation, Urine	OPICON	90370	Reference Range: Morphine, Urine: <10 ng/mL	1/29/2015
Pregnenolone	PREG	80398	Days Performed: Monday, Wednesday, Friday Reported: 3-6 Days Stability: Frozen: 3 Weeks Refrigerated: Unacceptable Ambient: Unacceptable Reference Range: MALE: 6-12 Months: 13-327 ng/dL 13-23 Months: 12-171 ng/dL 2-4 Years: 10-125 ng/dL 5-6 Years: 10-156 ng/dL 7-9 Years: 13-205 ng/dL 10-12 Years: 15-151 ng/dL 13-15 Years: 18-197 ng/dL 16-17 Years: 17-228 ng/dL 18-99 Years: 23-173 ng/dL Tanner Stage I: 13-156 ng/dL Tanner Stage II: 12-143 ng/dL Tanner Stage III: 16-214 ng/dL Tanner Stage IV-V: 19-201 ng/dL FEMALE: 6-12 Months: 13-327 ng/dL 13-23 Months: 12-171 ng/dL 2-4 Years: 15-125 ng/dL 5-6 Years: 13-191 ng/dL 7-9 Years: 14-150 ng/dL 10-12 Years: 19-220 ng/dL 13-15 Years: 22-210 ng/dL 16-17 Years: 22-229 ng/dL 18-99 Years: 15-132 ng/dL Tanner Stage I: 15-171 ng/dL Tanner Stage II: 22-229 ng/dL Tanner Stage III: 34-215 ng/dL Tanner Stage IV-V: 26-335 ng/dL	5/12/2015
Quantitative Pain Panel, Urine	UQNTPP	82347	Reference Range: Morphine, Urine: <10 ng/mL	1/26/2015
Rickettsia rickettsii IgG & IgM Abs	ROCKY	75478	Special Information: The best evidence for current infection is a significant change on two appropriately timed specimens, where both tests are done in the same laboratory at the same time. Methodology: Indirect Fluorescent Antibody (IFA) Clinical Information: The CDC does not use IgM results for routine diagnostic testing of Rocky Mountain Spotted Fever, as the response may not be specific for the agent (resulting in false positives) and the IgM response may be persistent from past infection. Please clearly label specimens. Days Performed: Tuesday-Friday Reported: 4-8 Days Components: Rocky Mt Spot Fev Ab IgG (ROCKIG) Rocky Mt Spot Fev Ab IgM (ROCKIM) Stability: Frozen: 1 Month (Avoid repeated freeze/thaw cycles) Refrigerated: 2 Weeks Ambient: 2 Days	5/12/2015
Rufinamide	RUFIN	88110	Stability: Frozen: 24 Months Refrigerated: 30 Days Ambient: 14 Days	5/4/2015

Test Changes (Cont.)

Test Name	Order Code	Billing Code	Change	Effective Date
T3 Uptake	T3U	77099	Specimen Requirements: 2.0 mL Serum - SST (Gold - 0.3 mL minimum); Refrigerated. Separate serum from cells within 2 hours of collection. <i>Alternate - 2.0 mL Serum - no additive (Red - 0.3 mL minimum);</i> Refrigerated. Separate serum from cells within 2 hours of collection. Methodology: Immunochemiluminometric Assay (ICMA) Days Performed: Monday-Saturday Reported: 3-4 Days Reference Range: 0-99 Years: 22.5-37.0 % Uptake Stability: Frozen: After separation from cells: 3 Months Refrigerated: After separation from cells: 1 Week Ambient: After separation from cells: 8 Hours	5/12/2015
Varicella-Zoster DFA	DVZV	77126	Days Performed: 7 Days a Week	2/24/2015

New Tests

Test Name	Order Code	Billing Code	Test Information	Effective Date
Allergen, Perch IgE	PERCH	90514	Specimen Requirements: 0.5 mL Serum - SST (Gold); Ambient. <i>Alternate</i> - 0.5 mL Serum - no additive (Red); Ambient. Methodology: Quantitative Conventional RAST Days Performed: Varies Reported: 4-7 Days CPT: 86003x1 Price: \$62.00	5/5/2015
Legionella Pneumophila, Antibody	SLEGAB	90510	Specimen Requirements: 0.5 mL Serum - no additive (Red - 0.4 mL minimum); Refrigerated. <i>Alternative</i> - 0.5 mL Serum - SST (Gold - 0.4 mL minimum); Refrigerated. Special Information: Evaluation of possible legionellosis (Legionnaires disease, Pontiac fever, extrapulmonary legionella infection caused by Legionella pneumophila). Methodology: Enzyme-Linked Immunosorbent Assay (ELISA) Clinical Information: Legionella pneumophila may cause pulmonary disease in both normal and immunocompetent hosts. The disease may occur sporadically in the form of community acquired pneumonia and in epidemics. Pneumonia (often referred to as Legionnaires disease) occurs more frequently in severely immunosuppressed individuals; a milder form of the illness, referred to as Pontiac fever, is more prevalent in normal hosts. Extrapulmonary infection with Legionella pneumophila is rare. Legionnaire's disease, Pontiac fever, and extrapulmonary infection have been collectively referred to as legionellosis. Approximately 85% of the documented cases of legionellosis have been caused by Legionella pneumophila. Serogroups 1 and 6 of Legionella pneumophila, by themselves, account for up to 75% of cases of legionellosis. The definitive diagnosis of Legionella pneumophila is made by isolation of the organism on specialized culture medium (buffered charcoal yeast extract agar). Pulmonary secretions can be directly examined using a direct fluorescent antibody procedure, but the sensitivity of this method is low (25%-70%). Often it is difficult for the patient to produce pulmonary secretion (sputum) for examination, the pneumonia is frequently interstitial and sputum is scant. In the absence of invasive procedures (e.g., bronchial alveolar lavage), urine evaluation for Legionella pneumophila antigen or indirect serological (antibody) methods may be useful. Days Performed: Monday, Wednesday, Friday Reported: 2-5 Days CPT: 86713x1 Price: \$62.00	5/5/2015

Fee Increases

Test Name	Order Code	Billing Code	List Fee	CPT Code	Effective Date
BK Virus Quantitation, Urine	UBKQT	82799	\$388.00	87799x1	4/1/15
Bromide, Blood	BROMWB	90122	\$135.00	80375x1	4/1/15
Hexosaminidase A & Total, WBC	TAYSAC	82868	\$458.00	83080x2	4/1/15
HLA B5701	B5701	84337	\$555.00	81381x1	4/1/15
Hyperoxaluria, Urine	UHYPER	87816	\$415.00	82544x1	4/1/15
L/S Ratio	LSRAT	77074	\$395.00	83661x1	4/1/15
Mycoplasma genitalium by PCR	MYGPCR	90072	\$452.00	87798x1	4/1/15
Tay-Sachs (Hexosaminidase)	HEX	76985	\$275.00	84999x1	4/1/15

Fee Reductions

Test Name	Order Code	Billing Code	List Fee	CPT Code	Effective Date
Cortisol, Saliva	SCORT	82629	\$59.00	82533x1	4/1/15
DHEA	DHEA	75487	\$100.00	82626x1	5/12/15
Fructosamine	FRUCTO	76672	\$54.00	82985x1	5/12/15
Inhibin A and B, Tumor Markers, Serum	INHAB	90078	\$250.00	86336x1 83520x1	1/27/15
Norovirus Group 1 and 2 Detection by PCR	NORPCR	89448	\$176.00	87798x2	3/23/15
Pregnenolone	PREG	80398	\$55.00	84140x1	5/12/15

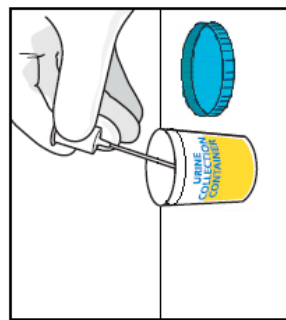
Discontinued Tests

Test Name	Order Code	Billing Code	Test Information	Effective Date
ACTA2 Gene Sequencing	ACTA2	88528	Test discontinued. Replaced by ACTA2G.	4/6/15
Adenovirus Antibodies	ADNOAB	75508	Test discontinued. Replaced by SADNAB.	2/17/15
Arbovirus Antibodies, IgG and IgM, Serum	ARBSER	90184	Test discontinued.	2/6/15
Narcolepsy Evaluation	NARCO1	82483	Test discontinued. NARCAB recommended replacement.	2/9/15
Transthyretin DNA Sequencing	TTRDNA	81481	Test discontinued. Replaced by TTRG.	4/6/15
VWD Type 2A, 2B, 2M Exon 28 Sequence Analysis	EXON28	82907	Test discontinued. Replaced by VWEX28.	4/6/15

Processing Urine Samples with BD Vacutainer® Collection Products



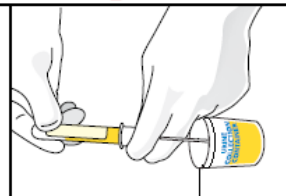
NAME: _____



1. Review the chart below.

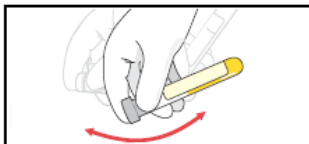
Tubes are collected based on the orders for culture or UA.

- Begin collection by submerging the tip of transfer straw into the specimen.



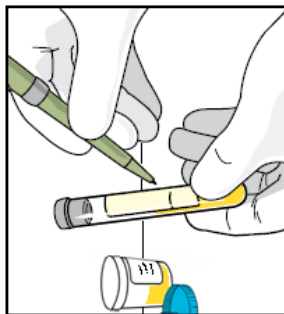
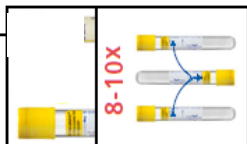
2. Push C&S Preservative Tube (grey top) into the transfer straw.

- Hold in position until flow stops.
- Remove tube, leaving transfer straw in specimen container.
- Shake tube vigorously.

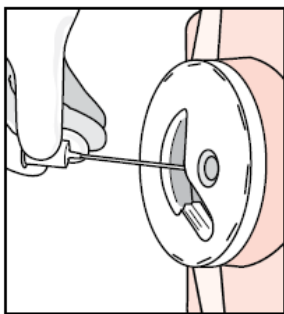


3. Push UA Preservative Tube into transfer straw completely.

- Hold in position until flow stops.
- Remove tube, leaving transfer straw in specimen container.
- Invert UA Preservative Tube 8-10 times to mix the sample.







4. Label any filled tubes with the patient's name, the date/time of specimen collection and any other data required.



5. Dispose of transfer straw in sharps collector.

- Send filled tubes to the lab for processing.
- DO NOT SEND CUP TO THE LAB UNLESS TESTS OTHER THAN UA AND/OR CULTURE ARE ORDERED.

FOR CULTURE	FOR URINALYSIS	USE WITH CUP	FOR FOLEY COLLECTION
 C & S Grey Top Tube BD # 364951 LAWSON #386505 PRESERVES URINE FOR 48 HOURS	 UA Preservative Tube Hemogard BD #365017 LAWSON #397614 PRESERVES URINE FOR 72 HOURS.	 Individually Wrapped Urine Collection Straws AMM 364956W-100 LAWSON #400873	 Luer-Lok™ Access Device BD #364902 LAWSON #154492 CONNECTS TO FOLEY PORT.