ClariTest® Core cfDNA Collection Tube

Please note that the next lot of ClariTest® Core cfDNA collection tubes is set to expire on **August 31, 2025**.

To avoid canceled test reports, please ensure that your phlebotomists or medical assistants check the expiration date on each tube prior to blood collection. We recommend not collecting blood within 2–3 days of the expiration date, as the tube must remain valid during transit and through the time of plasma isolation in our laboratory.

If a sample arrives at our laboratory on or after the expiration date, we will be unable to proceed with testing. A cancellation test report will be issued, noting that the sample arrived in an expired tube. This will require the patient to return for a second draw.

Test Name	Test Code	Effective Date
Patient Self-Collection for Sexually Transmitted Infections (STIs) and Vaginal Infections	**1004-1,1003 3,1006-8, TL75-6, TL79-8, TL76-4, M403-4**	**Immediately**

Patient self-collection of STI and vaginal infection specimens may be preferred in situations where the patient feels more comfortable collecting their own sample.

The Aptima® Multitest Swab Specimen Collection Kit is validated and approved by the U.S. Food and Drug Administration (FDA) for self-collection of certain sexually transmitted infections and vaginal infections.

IMPORTANT:

- Please note: It is required that the sample be collected within the healthcare facility (e.g., hospitals, clinics, doctors' offices, urgent care centers).
- The clinician or healthcare provider must review the collection instructions with the patient before the patient collects the sample in a healthcare facility setting.
- The sample collection tube must be labeled with the Patient's First and Last Name, and Date of Birth (DOB). The patient must confirm that all information on the tube label is correct before collecting the sample.
- The Aptima Multitest Swab Specimen Collection Kit is **NOT PERMITTED** for home collection use and **NOT PERMITTED** for collection in a Patient Service Center under any conditions.

	New Test Information
Primary Container	One (1) Aptima Multitest Swab. If ordering more than four test codes (CT/GC would be one multiplex), please supply two (2) Aptima Multitest Swabs.
Turn Around Time*	3 Days
Transportation Temp	Room Temperature

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Stability	Strictly 21 Days Room Temperature or Refrigerated
Methodology	Transcription Mediated Amplification
Reference Range	Not Detected
Collection Instructions	Instructions for collection can be found on the **Aptima Multitest Swab Specimen Collection Kit and/or Patient Collection Procedure Guide** available from the Sales Department.
CPT Code(s)**	Various (please visit our online test directory at https://www.bioreference.com/physicians/resources/test-directory/)

Test Name	Test Code	Effective Date
Mycoplasma Pneumoniae DNA Amplification Assay	**TS43-0**	**8/11/ 2025**

BioReference is pleased to offer the Mycoplasma Pneumoniae DNA Amplification Assay.

Mycoplasma Pneumoniae is a common cause of human upper and lower respiratory infections, including pharyngitis, acute bronchitis, and pneumonia.[1]

The Alethia Mycoplasma Direct DNA amplification assay[2], performed on the Alethia Reader, is a qualitative in vitro diagnostic test for the direct detection of DNA from Mycoplasma Pneumoniae in human throat swabs obtained from patients suspected of having Mycoplasma Pneumoniae infection.

- Results from the Alethia Mycoplasma Direct DNA amplification assay should be used in conjunction with clinical presentation, other laboratory findings, and epidemiological risk factors as an aid in the diagnosis of Mycoplasma infection. They should not be used as the sole basis for treatment or other patient management.
- Positive results do not rule out co-infection with other organisms, and negative results in persons with respiratory tract infections may be due to pathogens not detected by this assay.

References:
1. U.S. Centers for Disease Control and Prevention https://www.cdc.gov/mycoplasma/about/index.html Accessed August 8, 2025
2. National Library of Medicine https://accessgudid.nlm.nih.gov/devices/00840733102189 Accessed August 8, 2025

	New Test Information
Primary Container	E-swab (ES)
Turn Around Time*	1 Day
Transportation Temp	2-29° C Refrigerated
Stability	2-8° C: 14 Days Refrigerated; 19-29° C: 24 Hours Refrigerated
Methodology	LAMP DNA Amplification
Reference Range	Negative
Collection Instructions	Samples should be collected by vigorously swabbing the tonsils and the posterior pharynx. Swab sample(s) should be collected with E-Swab.
CPT Code(s)**	87581

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Test Name	Test Code	Effective Date
Varicella-Zoster Virus Antibodies, IgG and IgM (Retired)	**TS30-7**	**Immediately**

Test code TS30-7 Varicella-Zoster Virus Antibodies, IgG and IgM will no longer be offered effective immediately. The suggested alternate test is T008-2 Varicella-Zoster Antibody (VZV), IgG W/ Reflex to IgM (see below).

	Previous Test Information	New Test Information
Primary Container	SST	SST
Minimum Volume	0.5mL	1mL
Turn Around Time*	3-7 days	2 Days
Transportation Temp	Refrigerate	Refrigerate
Stability	14 days Refrigerate, 365 days Frozen	7 days Refrigerate
Methodology	Enzyme Linked Immunoabsorbance	Chemiluminescence
Reference Range	Varicella-Zoster Virus Antibody, IgM 0.90 ISR or less Varicella-Zoster Virus Ab, IgG <=0.99	>or=1.00 S/CO When Varicella IgG is negative, Varicella IgM will be performed at an additional cost.
CPT Code(s)**	86787x2	86787x1
Clinical Utility	May aid in diagnosing acute infections and detecting past exposure and/or vaccination.	Used to determine immunity.

Test Name	Test Code	Effective Date
Thyroid Stimulating Immunoglobulin (Retired)	**TG42-7**	**Immediately**

Test code TG42-7 will no longer be offered effective immediately. The suggested alternate test is TR39-0 Anti-Thyroid Stimulating Hormone Receptor (see below).

Test Name	Test Code	Effective Date
Anti-Thyroid Stimulating Hormone Receptor	**TR39-0**	**Immediately**

	Test Information
Primary Container	SST
Minimum Volume	1.0mL
Turn Around Time*	1 day
Transportation Temp	Refrigerate
Stability	6 days Refrigerated
Methodology	Electrochemiluminescence Immunoassay
Reference Range	<1.76 IU/L
Collection Instructions	SST: Fill tube, invert gently 5 times, label with patient name, let stand for a minimum of 30 minutes, maximum of 1 hr., spin for 10-15 minutes

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CPT Code(s)**	84235
Clinical Utility	The anti-TSH receptor determination is used in the assessment of patients suspected of Graves' Disease.

Test Name	Test Code	Effective Date
Breath Test for Detection of Helicobacter Pylori (H. pylori)	**TS46-3**	**8/25/2025**

BioReference® is pleased to offer Breath Test for Detection of Helicobacter Pylori effective on 8/25/2025. H. Pylori Breath test is intended for use to non-invasively measure changes in the $^{13}CO2/^{12}CO2$ ratio of exhaled breath, which may be indicative of increased urease production associated with active Helicobacter pylori (H. pylori) infection in the stomach.

New Test Information	
Primary Container	BBG – Breath Bag, Blue/Gray
Turn Around Time*	2 Days
Transportation Temp	15-30° C
Stability	14 Days Room Temperature
Reference Range	Negative
Collection Instructions	This test can only be performed on specimens from patients greater than or equal to 3 years old collected in Meridian breath collection bags. Sampling begins with the collection of a baseline breath sample. The patient inflates the Baseline Breath Sample Bag (blue). The patient then ingests a test drink consisting of ^{13}C-urea tablet 75mg and 4.3g of Citrica Powder (4g citric acid). After 15 minutes a post-ingestion sample is collected by inflation of the Post Ingestion Breath Sample Bag (Gray).
Methodology	Molecular Correlation Spectrometry
CPT Code(s)**	83013

Test Name	Test Code	Effective Date
HIV-1 Genotype Assay (Retired)	**J185-0**	**Immediately**

Test code J185-0 will no longer be offered effective immediately. The suggested alternate test is **TQ70-7 HIV-1 Genotyping (NRTI, NNRTI, PI, and INI) (see below).**

TQ70-7 HIV-1 Genotyping (NRTI, NNRTI, PI, and INI) helps identify drug resistance mutations in HIV-1 patients failing antiretroviral regimens that contain NRTI, NNRTI, PI, and INI. Additionally, HIV-1 Genotyping can identify transmitted drug resistance mutations in the PR, RT, and IN genes in treatment-naive patients prior to initiation of antiretroviral therapy.

Here we provide BioReference's testing algorithm for TQ70-7:

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- In a newly diagnosed patient, test code M396-0 HIV1, RNA, Ultra Quant PCR with Reflex to Genotype is suggested, which will run a quantitative viral load (test code 1010-8) and if = or >500 copies/ml will reflex to the HIV-1 genotype (test code TQ70-7).

- When TQ70-7 is ordered by itself, test results of viral load must be provided (or performed) within the previous two weeks. The viral load must be = or >500 copies/mL for TQ70-7 to be run.

- When TQ70-7 is requested as an add-on to a quantitative viral load (1010-8 HIV-1, RNA, Ultra/PCR, Viral Load), if the viral load is <500 copies/mL, TQ70-7 will not be performed.

Abbreviations:
NRTI - Nucleoside/Nucleotide Reverse Transcriptase Inhibitor; NNRTI - Non-Nucleoside Reverse Transcriptase Inhibitor; PI - Protease Inhibitors; INI - Integrase Inhibitor; PR – Protease; RT – Reverse Transcriptase; IN - Integrase

New Test Information	
Primary Container	ALQE - Aliquot Plasma-EDTA-Lavender Top
Minimum Volume	4 mL
Turn Around Time*	10 Days
Transportation Temp	Frozen
Stability	42 Days Frozen
Collection Instructions	Lavender Top Tubes and White Top PPT tubes are NOT accepted frozen. **Only aliquot plasma can be submitted frozen.**
Methodology	Reverse Transcription Polymerase Chain Reaction
CPT Code(s)**	87900, 87901, 87906

URINE TOXICOLOGY TEST MENU CHANGES:

Test Name	Test Code
Lorazepam (ATIVAN), Urine (Retired)	**5924-6**
Alprazolam and Metabolite, Urine (Retired)	**3864-6**
Drug Confirmation, Clonazepam, Urine (Retired)	**L204-7**

Test codes 5924-6, 3864-6, and L204-7 will no longer be offered effective immediately. The suggested alternate test is 3105-4 Drug Confirmation, Benzodiazepines, Urine (see below).

Test Name	Test Code
Drug Confirmation, Benzodiazepines, Urine	**3105-4**

New methodology, reference range, and panel components added.

	Previous Test Information	New Test Information
Methodology	Gas Chromatography Mass Spectrometry (GC/MS)	Liquid Chromatography-Tandem Mass Spectrometry (LC/MS/MS)

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Reference Range	<200 ng/mL	<50 ng/mL
Panel Components	Nordiazepam Alpha-OH-alprazolam Temazepam Oxazepam	Nordiazepam (test code A770-0; LOINC 16228-9) Alpha-OH-alprazolam (test code A773-4; LOINC 16348-5) Temazepam (test code A772-6; LOINC 20559-1) Oxazepam (test code A771-8; LOINC 16201-6) Lorazepam (test code TR94-5; LOINC 17088-6) Alprazolam (test code TR93-7; LOINC 59615-5) 7-Aminoclonazepam (test code J921-8; LOINC 51776-3) Clonazepam (test code J910-1; LOINC 16229-7)

Test Name	Test Code
Methylenedioxymethamphetamine and Metabolite, Urine (Retired)	**3490-0**
Test code 3490-0 will no longer be offered effective immediately. The suggested alternate test is M482-8 Drug Confirmation, MDMA (Methylenedioxymethamphetamine), Urine (see below).	

Test Name	Test Code
Drug Confirmation, MDMA (Methylenedioxymethamphetamine), Urine	**M482-8**
New test for confirmation of MDA (3, 4-methylenedioxyamphetamine), MDMA (Methylenedioxymethamphetamine), and MDEA (Methylenedioxyethylamphetamine).	

	New Test Information
Primary Container	USC- Urine Cup
Minimum Volume	5 mL
Turn Around Time*	4 Days
Transportation Temp	Refrigerated
Stability	7 days Refrigerated
Methodology	Liquid Chromatography-Tandem Mass Spectrometry (LC-MS/MS)
Reference Range	<50 ng/mL
Panel Components	MDA (3,4-methylenedioxyamphetamine) (test code TR84-6; LOINC 20545-0) MDMA (Methylenedioxymethamphetamine) (test code TR82-0; LOINC 18358-2) MDEA (Methylenedioxyethylamphetamine) (test code TR83-8; LOINC 45143-5)
CPT Code(s)**	80359 x 1

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Test Name	Test Code
Tramadol, Confirm, Urine (Retired)	**B704-8**

Test code B704-8 will no longer be offered effective immediately. The suggested alternative test is M483-6 Drug Confirmation, Tramadol, Urine (see below)

Test Name	Test Code
Drug Confirmation, Tramadol, Urine	**M483-6**

New test for confirmation of Tramadol and O-Desmethyl-cis-tramadol.

	New Test Information
Primary Container	USC – Urine Cup
Minimum Volume	5 mL
Turn Around Time*	4 Days
Transportation Temp	Refrigerated
Stability	7 Days Refrigerated
Methodology	Liquid Chromatography-Tandem Mass Spectrometry (LC/MS/MS)
Reference Range	<50 ng/mL
Panel Components	Tramadol (test code TR85-3; LOINC 20561-7) O-Desmethyl-cis-tramadol (test code TR86-1; LOINC 92639-4)
CPT Code(s)**	80373 x 1

Test Name	Test Code
Zolpidem and Metabolites, Urine (Retired)	**A900-3**

Test code A900-3 will no longer be offered effective immediately. The suggested alternate test is M484-4 Drug Confirmation, Zolpidem, Urine (see below).

Test Name	Test Code
Drug Confirmation, Zolpidem, Urine	**M484-4**

New test for confirmation of Zolpidem and Zolpidem phenyl-4-carboxylic acid.

	New Test Information
Primary Container	USC – Urine Cup
Minimum Volume	5 mL
Turn Around Time*	4 Days
Transportation Temp	Refrigerated
Stability	7 Days Refrigerated

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Methodology	Liquid Chromatography-Tandem Mass Spectrometry (LC/MS/MS)
Reference Range	<5 ng/mL
Panel Components	Zolpidem (test code TR87-9; LOINC 72770-1) Zolpidem phenyl-4-COOH (test code TR88-7; LOINC 72768-5)
CPT Code(s)**	80368 x 1

Test Name	Test Code
Drug Confirmation, Methadone, Urine (Retired)	3106-2

Test code 3106-2 will no longer be offered effective immediately. The suggested alternate test is M481-0 Drug Confirmation, Methadone, Urine (see below).

Test Name	Test Code
Drug Confirmation, Methadone, Urine	M481-0

New methodology, reference range, and panel components added.

	Previous Test Information	New Test Information
Methodology	Gas Chromatography Mass Spectrometry (GC/MS)	Liquid Chromatography-Tandem Mass Spectrometry (LC/MS/MS)
Reference Range	<200 ng/mL	<50 ng/mL
Panel Components	Methadone	Methadone (test code 3106-2; LOINC 16246-1) EDDP (2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine) (test code TR95-2; LOINC 58429-2)

Test Name	Test Code
Drug Confirmation, Phencyclidine, Urine (Retired)	3108-8

Test code 3108-8 will no longer be offered effective immediately. The suggested alternate test is M487-7 Drug Confirmation, Phencyclidine, Urine (see below).

Test Name	Test Code
Drug Confirmation, Phencyclidine (PCP), Urine	M487-7

New test confirmation for Phencyclidine.

	New Test Information
Primary Container	USC – Urine Cup
Minimum Volume	5 mL
Turn Around Time*	4 Days

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Transportation Temp	Refrigerated
Stability	7 Days Refrigerated
Methodology	Liquid Chromatography-Tandem Mass Spectrometry (LC/MS/MS)
Reference Range	<25 ng/mL
Panel Component	Phencyclidine (PCP) (test code 3108-8; LOINC 16254-5)
CPT Code(s)**	83992 x 1

Urine Toxicology Tests with Changes to Methodology, Reference range, Panel components:

Test Name	Test Code
Drug Confirmation, Oxycodone, Urine	**A204-0**

New methodology, reference range, and panel components added.

	Previous Test Information	New Test Information
Methodology	Gas Chromatography Mass Spectrometry (GC/MS)	Liquid Chromatography-Tandem Mass Spectrometry (LC/MS/MS)
Reference Range	<300 ng/mL	<50 ng/mL
Panel Components	Oxycodone Oxymorphone	Oxycodone (test code B114-0; LOINC 16249-5) Oxymorphone (test code B115-7; LOINC 17395-5) Noroxycodone (test code TR89-5; LOINC 61425-5)

Test Name	Test Code
Drug Confirmation, Hydrocodone, Urine (Retired)	**6327-1**

Test code 6327-1 will no longer be offered effective immediately. The suggested alternate code is 2596-5 Drug Confirmation, Opiates, Urine (see below).

Test Name	Test Code
Drug Confirmation, Opiates, Urine	2596-5

New methodology, reference range, and panel components added.

	Previous Test Information	New Test Information
Methodology	Gas Chromatography Mass Spectrometry (GC/MS)	Liquid Chromatography-Tandem Mass Spectrometry (LC/MS/MS)
Reference Range	<300 ng/mL	<50 ng/mL
Panel Components	Morphine Codeine Hydrocodone	Morphine (test code A775-9; LOINC 16251-1)

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	Hydromorphone	Codeine (test code A774-2; LOINC 16250-3) Hydrocodone (test code A776-7; LOINC 16252-9) Hydromorphone (test code A777-5; LOINC 16998-7) Norhydrocodone (test code TR81-2; LOINC 61422-2)

Test Name	Test Code
Drug Confirmation, Cocaine, Urine	M485-1

New methodology, reference range, and panel components added.

	Previous Test Information	New Test Information
Methodology	Gas Chromatography Mass Spectrometry (GC/MS)	Liquid Chromatography-Tandem Mass Spectrometry (LC/MS/MS)
Reference Range	<200 ng/mL	<50 ng/mL
Panel Components	Benzoylecgonine	Benzoylecgonine (test code 3104-7; LOINC 19358-1) Cocaine (test code TR90-3; LOINC 20519-5) Cocaethylene (test code TR91-1; LOINC 16632-2)

Test Name	**Test Code**
Drug Confirmation, Amphetamines, Urine	**3101-3**

New reference range for Amphetamine and Methamphetamine.

	Previous Test Information	**New Test Information**
Reference Range	<500 ng/mL	<50 ng/mL

Test Name	Test Code
Drug Confirmation, Fentanyl, Urine	M237-6

New reference range.

	Previous Test Information	**New Test Information**
Reference Range	<1 ng/mL	<5 ng/mL

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Test Name	Test Code
Drug Confirmation, 6-MAM, Urine	**M488-5**
New methodology.	

	Previous Test Information	New Test Information
Methodology	Gas Chromatography Mass Spectrometry (GC/MS)	Liquid Chromatography-Tandem Mass Spectrometry (LC/MS/MS)

Urine Toxicology New Test Offering:

Test Name	Test Code
Drug Confirmation, Opioid, Urine	**M480-2**
New test for confirmation of Naloxone.	

	New Test Information
Primary Container	USC – Urine Cup
Minimum Volume	5 mL
Turn Around Time*	4 Days
Transportation Temp	Refrigerated
Stability	7 Days Refrigerated
Methodology	Liquid Chromatography-Tandem Mass Spectrometry (LC/MS/MS)
Reference Range	<10 ng/mL
Panel Component	Naloxone (test code TR92-9; LOINC 77207-9)
CPT Code(s)**	80368 x 1

Questions? Please contact your Account Executive or Customer Service directly at 800-229-5227.

Best regards,
The BioReference® Team

*TAT is based upon receipt of the specimen at the laboratory.
**CPT codes provided are based on AMA guidelines and are for informational purposes only. CPT coding is the sole responsibility of the billing party. Please direct any questions regarding coding to the payer being billed.

Healthcare providers should only order panels if each test in the panel is medically necessary.

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