alethia®

C. difficile

Provides physicians with accurate and reliable results, allowing for appropriate management and treatment of their patients

C. difficile - The Continuous Threat

More than half of all hospitalized patients might get an antibiotic at some point during their hospital stay, but 30 to 50% of those prescribed in hospitals are unnecessary or incorrect, putting patients at risk for *C. difficile* infections[1]

Alethia® helps improve patient management by providing accurate and reliable results for the detection of *C. difficile*

- Reduce the risk of missing a true positive with the accuracy of molecular
- Fast, actionable results enable physicians to make informed decisions about the patient management and treatment resulting in reduced healthcare costs associated with isolation and antibiotics
- Alethia® is a flexible, reliable molecular platform that allows health systems to provide testing closer to the patient

Your lab can improve outcomes for patients suspected of having CDI

- What steps is your facility taking to minimize the burden of *C. difficile*?
- How would a fast, accurate result help you improve outcomes and satisfaction among patients and physicians?

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C. difficile

Alethia® is a flexible molecular platform that can help standardize testing throughout a health system improving clinical efficiencies

Meridian's *C. difficile* testing solutions allow health systems to standardize testing to one vendor across the network and improve overall operational efficiency

Customize a diagnostic approach to fit your unique needs by partnering with the only company to provide the complete *C. difficile* testing portfolio.

Product Specifications

The Alethia® *C.difficile* assay is a qualitative *in vitro* diagnostic test for the direct detection of toxigenic *C. difficile* in human stool specimens from pediatric and adult patients suspected of having *Clostridium difficile*-associated disease (CDAD).

Turnaround Time

Less than one hour

Sample Type

Unformed stool specimens

Sample Storage

- Unpreserved samples: 21-27C for up to 24 hours
- 2-8 C for up to 5 days
- Preserved stools: 2-8 C for up to 5 days

Kit Storage

2-27 C until expiration date indicated on kit label

Performance

95.2% Sensitivity

95.3% Specificity

Catalog Number

Alethia® *C. difficile* Assay — 480050

CPT Codes

87493

References

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Ready to get a handle on *C. difficile* testing? Let's talk.

Contact a specialist at 1-888-763-6769.

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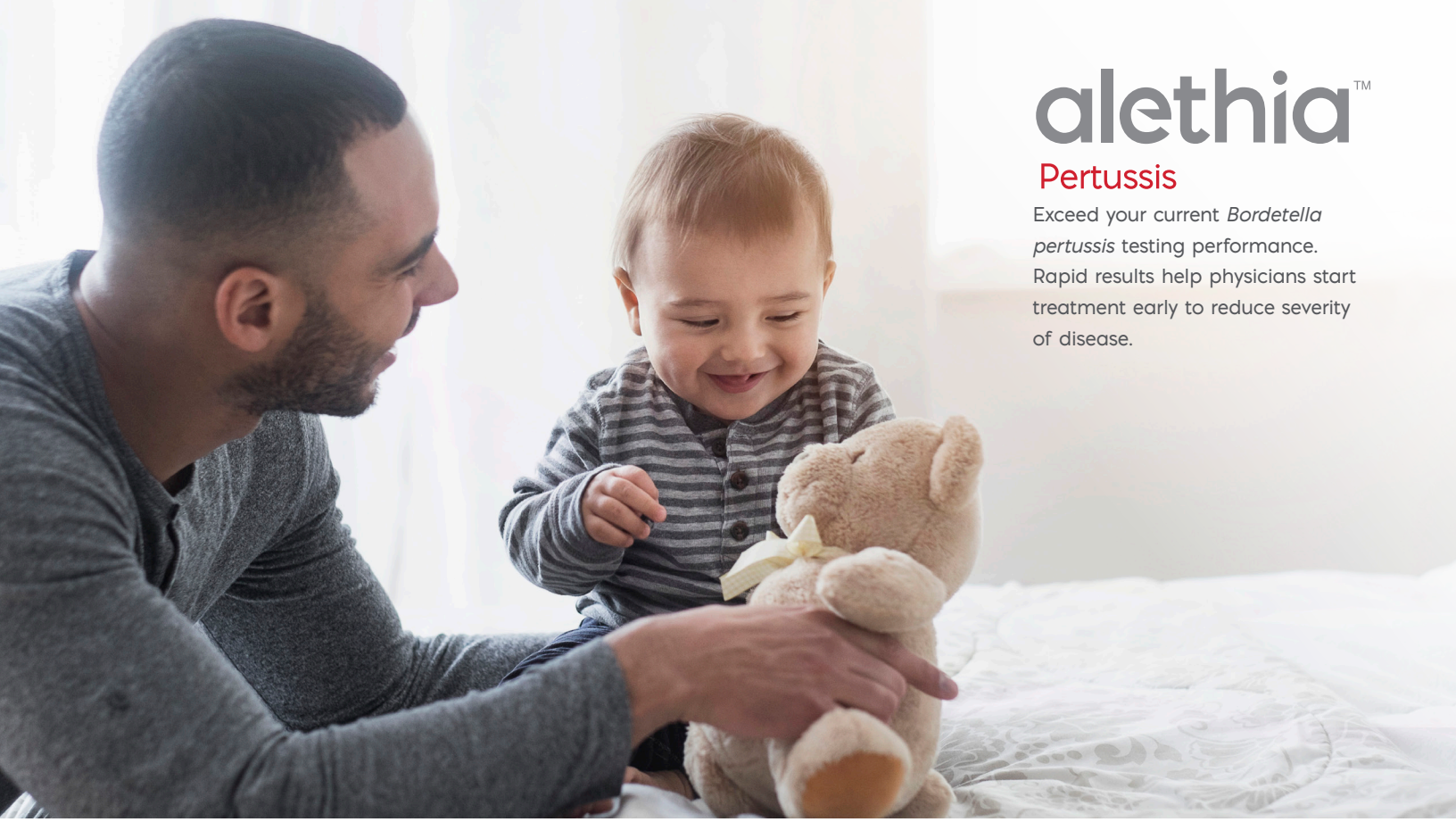

alethia™

Pertussis

Exceed your current *Bordetella pertussis* testing performance. Rapid results help physicians start treatment early to reduce severity of disease.

Alethia™ Pertussis – Rapid and targeted detection for *Bordetella pertussis*

The CDC, IDSA and AAP recognize molecular testing as an important tool to diagnose B. pertussis[1,2] due to improved sensitivity and rapid turnaround time.[1]

Traditional culture requires a 7-10-day turnaround, has a variable sensitivity (12-60%) and requires subjective analysis. Send-out costs and delayed results are a burden on the laboratory.[3,4]

- In recent years, there have been more reported cases of *Bordetella pertussis* (Whooping Cough) in the U.S. than any other time since 1955.[5]
- Studies indicate vaccinations for *Bordetella pertussis* don't always provide lifelong protection.[7]
- Alethia Pertussis has a simple procedure with low invalid rates that eliminate the need for repeat testing.

Is your current testing method accurate?

- How do missed positives affect patient treatment?
- How long does it take your lab to get results with your current method?

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Pertussis

Results that Matter

- With molecular results in less than one hour, long turnaround times and send out costs can be eliminated.

Improve Outcomes for Patients

- *Bordetella pertussis* illness can be clinically indistinguishable from other respiratory infections.[6]
- Targeted detection can help physicians treat patients appropriately.
- The molecular accuracy of Alethia Pertussis provides a clear and objective evaluation of positive/ negative test results. This can help to reduce the risk of spreading illness to others and allow for appropriate treatment as soon as possible.

Product Specifications

The Alethia™ Pertussis DNA Amplification Assay is a qualitative in vitro diagnostic test for the direct detection of *Bordetella pertussis* in human nasopharyngeal swab samples taken from patients suspected of having respiratory tract infection attributable to *Bordetella pertussis*

Turnaround Time

Less than one hour

Shelf Life

18 months

Sample Type

Nasopharyngeal swabs

Sample Storage

- Samples should be placed in a non-nutritive transport medium or can be stored unpreserved in a sterile tube without medium.
- Samples may be held at room temperature 21-30C for up to 5 days or refrigerated 2-8C for up to 7 days prior to testing

Kit Storage

Kits should be stored at 2-30C

Performance

Performance characteristics of the assay were compared to culture.

87.8% PPA

97.8% NPA

Catalog Number

Alethia™ Pertussis Assay — 480750

Alethia™ Pertussis External Control Kit — 479930

CPT Codes

87798

References

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2. Baron, Ellen Jo, et al. "A Guide to Utilization of the Microbiology Laboratory for Diagnosis of Infectious Diseases: 2013 Recommendations by the Infectious Diseases Society of America (IDSA) and the American Society or Microbiology (ASM) a." Clinical Infectious Diseases 57.4 (2013): e22-e121.
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7. https://www.cdc.gov/vaccines/vpd/dtap-tdap-td/public/index.html

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MBI_Alethia_Pertussis_SS_2019-04

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CMV

Improve outcomes for physicians by providing a convenient and timely result for congenital CMV in newborns.

Congenital CMV – The Unknown Threat to Newborns

Nearly 1 in 4 women are carriers of the most common virus passed from mother to babies during pregnancy[1,2]. Every year 1 in 200 babies are born with cCMV[3], and yet, the majority of pregnant women have never heard of it.

Alethia™ CMV provides early detection of congenital CMV which is vital in guiding appropriate treatment for newborns.

- Report results with confidence with the First FDA cleared test for cCMV
- Utilizes saliva, an easy to collect and preferred sample type for congenital CMV testing[4]
- Obtain results in less than one hour with minimal hands on time
- High NPV provides confidence to physicians and piece of mind to parents before their baby goes home

Your lab can improve outcomes for newborns.

- How would an FDA cleared cCMV test with a simple procedure and results in less than one hour help improve turnaround time and overall lab workflow?
- Knowing cCMV is the leading cause of deafness in newborns, how would you implement a test in your health system that can impact patient care and reduce costs associated with potential disease complications?

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CMV

Results That Matter

- The simple procedure of Alethia CMV provides flexibility to best fit the laboratory's workflow when compared to other testing technologies.
- Saliva is easy to collect and contains high viral load, allowing optimal detection and same day reporting for physicians and families.

Improving Outcomes For Newborns

- Implementing newborn testing strategies for cCMV have been increasingly recognized for their potential medical benefits and improved patient outcomes.[5]
- Congenital CMV testing empowers physicians and families with the full understanding of their newborn's health prior to leaving the hospital.

Product Specifications

Intended Use
The Alethia CMV Assay is an in vitro diagnostic molecular test for the detection of CMV from the saliva of newborns under 21 days. The test will provide an actionable result to enable the clinical team to develop an appropriate treatment plan.

Turnaround Time
< 60 minutes

Sample Type
Saliva from newborns younger than 21 days

Sample Storage
- Saliva swabs can be stored at 19 - 30 C up to 48 hours.
- Refrigerated at 2 - 8 C up to 7 days.
- Frozen at ≤ -20C up to 14 days.

Kit Storage
Kit should be stored at 19 - 30 C

Performance
100% PPA

99.8% NPA

Catalog Number
Alethia CMV - 481325

Alethia CMV
External Control - 479880

CPT Codes
87496

References
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3. Congenital CMV Facts. Centers for Disease Control and Prevention. https://www.cdc.gov/features/cytomegalovirus/index.html. Published 2018. Accessed October 17,
4. Congenital cytomegalovirus infection in pregnancy and the neonate: consensus recommendations for prevention, diagnosis, and therapy William D Rawlinson, www.thelancet.com/infection Published online March 10, 2017 http://dx.doi.org/10.1016/S1473-3099(17)30143-3
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MBI_Alethia_CMV_SS_2018-12

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Mycoplasma Direct

Improves decision making for physicians by providing a convenient and timely result for *Mycoplasma pneumoniae*

When Your Current Method Doesn't Provide Clear Results, it's time to change the way you test.

There are an estimated 2 million cases of *Mycoplasma pneumoniae* annually in the US. Of these, X-rays only identify 30% of positives[1] and serology may only detect about 25%[2].

Alethia™ Mycoplasma Direct takes the guessing out of an accurate identification of *Mycoplasma pneumonia* infection with a targeted diagnosis from day one of symptoms.

- Report results with certainty and empower physicians to properly treat their patients.
- Single target molecular testing is more sensitive than X-ray, serology and multiplex molecular.
- With minimal hands-on time and an easy to collect throat swab, your lab can deliver qualitative results in less than one hour.

Is your health system missing positives?

- How well do you maximize the use of your financial and technical resources?
- How well does your current test method detect *Mycoplasma pneumoniae*?

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Mycoplasma Direct

Results that Matter

- Improve patient outcomes by reducing the chance of a missed positive and minimizing risk of spreading the disease.
- Alethia Mycoplasma direct can deliver targeted detection so physicians can treat patients appropriately.

Improved performance over traditional methods

- Definitive diagnosis of Mycoplasma cannot be made on the basis of image alone. A combination of clinical and radiographical findings can significantly improve accuracy of disease diagnosis.[3]
- Chest X-rays may be negative, particularly in patients presenting in early disease course and among the elderly.[4] *Mycoplasma pneumoniae* is often difficult to recognize on X-rays.[5]

Product Specifications

Alethia™ Mycoplasma Direct DNA amplification assay 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.

Turnaround Time

Less than one hour

Shelf Life

18 months

Sample Type

Throat swabs placed in a non-nutritive transport medium

Sample Storage

- Samples should be placed in a non-nutritive transport medium containing pledget and held at 2-29 C during transport
- Samples may be held at room temperature (19-29 C) for up to 24 hours or refrigerated (2-8 C) for up to 14 days prior to testing

Kit Storage

Kits should be stored at 2-27 C

Performance

Performance characteristics of the assay were compared to culture.

96.0% PPA

97.7% NPA per PI

Catalog Number

Alethia™ Myco Direct
Test - 480250

Alethia™ Myco Direct
External Control - 479890

CPT Codes

87581

References

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Know when to treat.

Differentiate Group A Strep from viral pharyngitis. Up to 70% of patients receive antibiotic therapy while only 20 - 30% have Group A Strep pharyngitis.[1]

Improve decision making for physicians by providing a convenient and timely result of Group A Strep pharyngitis.

- Acute pharyngitis is one of the most frequent illnesses for which pediatricians are consulted.
- An estimated 15 million Group A Strep visits per year in the U.S. have an annual economic impact of $224-$539 million.

How well does your current method detect Group A Strep?

- How well do you maximize the use of your financial and technical resources?
- How how well does your test method determine the need for antibiotic treatment?

alethia™
Group A Streptococcus

immunocard STAT!®
Strep A

alethia™
Group A Streptococcus

Increased Detection with Simple Workflow

- Alethia Group A Strep can help prevent unncessary antibiotic treatment which can lead to the development of antimicrobial resistance among common pathogens[1]
- The accuracy and speed of Alethia Group A Strep results helps families return to their busy daily routines as quickly as possible
- Alethia Group A Strep molecular amplification has a 98% sensitivity that has shown to be 53% more sensitive than traditional culture

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Product Specifications

Intended Use

The Alethia Group A *Streptococcus* assay, is a qualitative invitro diagnostic test for the detection of *Streptococcus* pyogenes (Group A β-hemolytic *Streptococcus*) in throat swab specimens.

Turnaround Time

Less than 60 minutes

Shelf Life

18 months

Sample Type

Throat swabs placed in non-nutritive transport medium

Sample Storage

- Samples should be held at 2 - 27 C during transport
- Samples may be held at 21 - 27 C for up to 48 hours prior to testing
- Stored at 2 - 8 C for up to 7 days

Kit Storage

Kit should be stored at 2 - 27 C

Performance

Performance characteristics of the assay were compared to culture.

98.0% Sensitivity

97.7% Specificity

Catalog Number

Alethia Group A Streptococcus Test - 480150

Alethia Group A Streptococcus External Control - 479910

CPT Codes

87651

Increased detection of positives by 53%, over traditional culture

immunocard STAT!®
Strep A

Near Patient Testing

- CLIA Waived, easy to use technology
- Rapid test for detection of Group A Streptococcal Antigen from throat swabs
- Results in five minutes, shortening patient wait time

Increased Detection with Simple Workflow

- Test with Immunocard STAT! Strep A first and be able to treat while patient is waiting
- Reflex Rapid Group A Strep negatives to the Alethia Group A Strep molecular to confirm results

A Meridian Group A Strep user noted, "We had a Group A Strep patient who was negative on the rapid test and we (culture) plated it. A Meridian Group A Strep customer explained, "We also ran it on Meridian's molecular test, which showed it was positive and then we were able to notify the physician right away. After 24 hours, we didn't see enough (culture) growth to type it, so we incubated for another 24. Finally, on the third day, it (culture plate) was positive..... the patient had an answer in 1 hour vs. 2 days! That made it very clear that the molecular test would make a difference in our patient care."

One Meridian Group A Strep customer noted, "now physicians can run a rapid test in their office, send negatives to us and have definitive results in 2 hours so that antibiotics aren't prescribed when unnecessary."

Product Specifications

Intended Use

The Immunocard STAT! Strep A test is intended for the qualitative detection of Group A Streptococcal antigen from throat swabs or confirmation of presumptive Group A Streptococcal colonies recovered from culture.

Turnaround Time

Less than 5 minutes

Shelf Life

10 months

Sample Type

Throat swabs placed in non-nutritive transport medium

Sample Storage

- Test immediately, or store at room temperature or refrigerated for up to 48 hours

Kit Storage

Kit should be stored at 15 - 30 C

Performance

Performance characteristics of the assay were compared to culture.

96.0% Sensitivity

97.8% Specificity

Catalog Number

Immunocard STAT!
Strep A Test - 755250

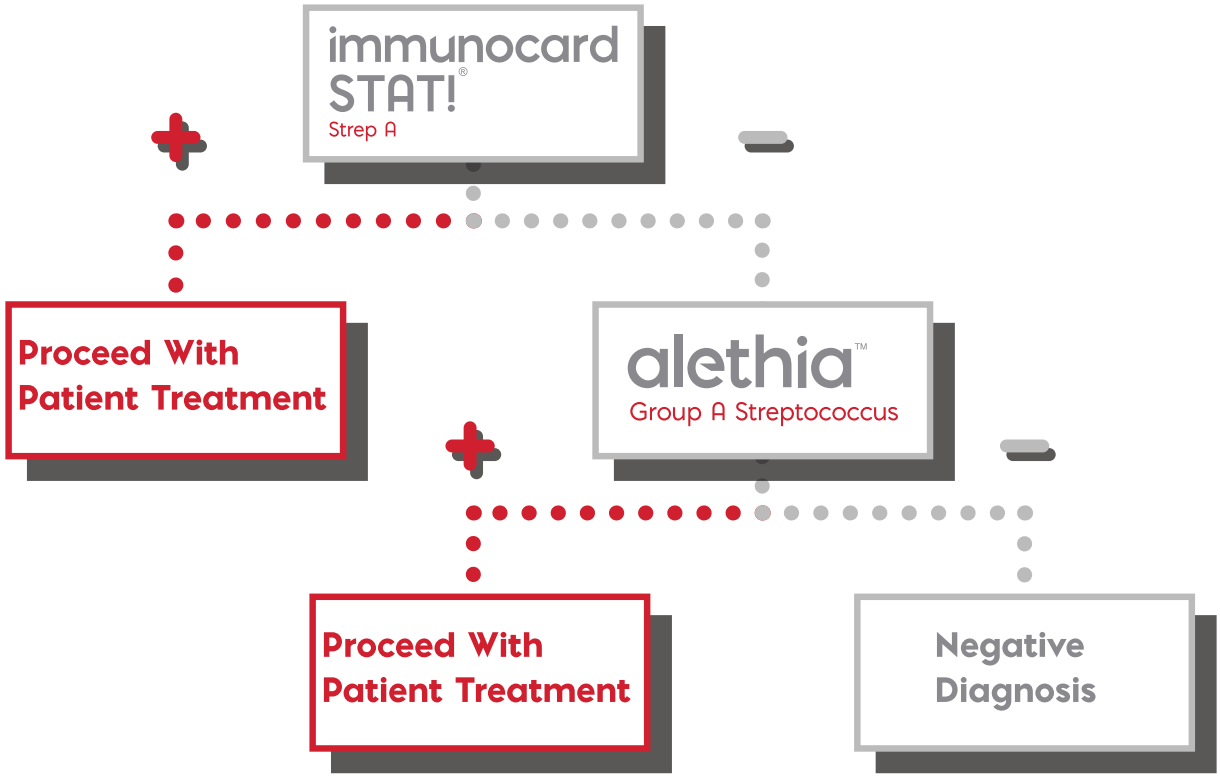
CPT Codes

87880

Simple procedure with minimal hands on time

Meridian's Group A Strep
Best of Both Worlds Solution

A Near Patient Solution To Meet Your Testing Needs



Best of Both Worlds Promotion Includes:

Product Package	Kit Quantity	Kit Size	Promo Code
Immunocard STAT!® Strep A	3	50 Test / Kit	280150P23
Alethia™ Group A Strep	2	50 Test / Kit	

References

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2. Alethia Group A Strep Package insert, SN11022
3. Immunocard® STAT! Strep A Package Insert, REV. 3856-5

Ready to get a handle on Group A Strep testing? Let's talk.

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Group B Streptococcus

Provides physicians with accurate and reliable results, allowing for appropriate treatment decisions of mother at time of delivery, ensuring best outcome for baby

Care for Them with Certainty

The Alethia™ Platform from Meridian Bioscience helps you provide molecular accuracy when testing for GBS in expectant mothers.

Most infants who develop GBS disease are born to mothers who tested negative for Group B Strep.

- Culture sensitivity has been shown to be unreliable and is documented to be as low as 42%.
- Broth enrichment and Alethia™ Group B Strep increased detection of positives by up to 29% over culture for the detection of Group B *Streptococcus*.
- Pregnant moms and their families are hoping for a joyful birth experience. Give your labs and expectant mothers peace of mind with a definitive answer from the Alethia Group B Strep test.

If your lab currently screens for GBS with culture, the implications could be significant:

- Can you trust your negative culture and ensure your lab doesn't miss a non-hemolytic GBS strain?
- What are the implications of missing a GBS positive?

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Group B Streptococcus

The molecular precision of Alethia Group B Strep test ensures accurate results and timely administration of appropriate antibiotic therapy for GBS-positive patients.

Increased Confidence and Decreased Laboratory Burden

"We want to catch them all."

One Meridian Group B Strep user noted in their experience, 5% of GBS strains are non-β-hemolytic, and it was important to the staff to have this added level of sensitivity. Using Meridian's GBS test optimized their ability to maintain this level of care *and was of utmost* importance to the lab.

"It's given me so much peace."

Product Specifications

Intended Use

The Alethia Group B *Streptococcus* assay is a qualitative in vitro diagnostic for the detection of *Streptococcus agalactiae* in enriched cultures obtained from vaginal/rectal swab specimens from antepartum women.

Turnaround Time

Less than one hour, after broth enrichment

Shelf Life

18 months

Sample Type

Vaginal/rectal swab specimens, antepartum

Sample Storage

- Samples should be placed in a non-nutritive transport medium.
- Sample should be removed from the transport device and placed in culture enrichment broth (LIM Broth, TransVag Broth or Carrot Broth).
- Enriched samples may be held at room temperature for up to 6 hours prior to testing.
- Enriched samples may be held at 2—8 C for up to 7 days prior to testing.

Kit Storage

Kit should be stored at 2 - 27 C

Performance

Performance characteristics of the assay were compared to culture.

98.6% Sensitivity

93.2% Specificity

Catalog Number

Alethia™ Group B Streptococcus - 480350

Alethia™ Group B Streptococcus External Control - 279900

CPT Codes

87081, 87653

References

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Malaria

Improves decision making for your clinicians by providing an accurate and timely laboratory result for malaria.

THE BETTER WE ARE AT DETECTING MALARIA, THE BETTER OUR ODDS OF BEATING IT. FOR GOOD.

Approximately 219 million cases of malaria still occurred worldwide[1] and diagnostic testing and treatment is a key component of malaria control in either endemic and non-endemic areas. When malaria claims one life every minute, it's time to change the way you test!

Prompt diagnosis and treatment is the most effective way to prevent a mild case of malaria from developing into severe disease and death

- Let your labs screen negative results with confidence. Alethia Malaria has an analytical sensitivity of up to 80,000x more than conventional methods[1,3]
- Avoid delays in treatment with quick and precise results in less than one hour

Revolutionize your laboratory's diagnostic accuracy with molecular performance

- With no special training or technical expertise required, Alethia Malaria provides your laboratory with a simple yet affordable molecular assay readily deployable in the field.

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Malaria

Results That Matter

- Alethia Malaria allows for the direct detection of *Plasmodium spp.* (*P. falciparum, P. vivax, P. ovale, P. malariae, and P. knowlesi*), with up to 1,500x better analytical sensitivity than microscopy[2,3] and up to 80,000x better analytical sensitivity than RDT's[2,4]
- Remove the human subjectivity from malaria diagnosis

Fast & Streamlined

- The molecular precision of Alethia Malaria eliminates the need for repeat tests, allowing you to save time and money in the laboratory.
- Deliver a timely result with a simple 2 minute sample preparation from whole blood, and 40 minutes of amplification time.

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Product Specifications

The Alethia™ Malaria DNA amplification assays, performed on the Alethia Incubator/Reader™, are qualitative in vitro diagnostic tests for the direct detection of *Plasmodium sp.* DNA in human venous EDTA whole blood specimens from individuals with signs and symptoms of malarial infection. Results from Alethia Malaria assays are intended to be used as an aid in the diagnosis of human malaria infection.

Turnaround Time

Less than 45 minutes

Shelf Life

12 months

Sample Type

Human venous whole blood samples with EDTA as a preservative

Sample Storage

- EDTA venous whole blood samples may be stored up to 7 days at room temperature 19-30 C
- Up to 14 days refrigerated 2-8 C prior to testing.
- Up to 30 days frozen at < -20 C

Kit Storage

Kit should be stored at 2 — 30 C

Performance

Analytical Sensitivity

2 Parasite/µl

Clinical Sensitivity

100% Sensitivity

Catalog Number

Alethia™ Malaria - 480925

Alethia™ Malaria PLUS - 481125

Alethia™ Malaria
External Control - 479970

References

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3. Okell LC, Ghani AC, Lyons E, Drakeley CJ. Submicroscopic infection in Plasmodium falciparum-endemic populations: a systematic review and meta-analysis. J Infect Dis 2009; 200:1509
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Molecular Ends Malaria. It's time to talk.

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MBI_Alethia_Malaria_SS_ 2019-05

alethia®

HSV 1&2

Improves decision making for physicians with results that differentiate HSV-1 and HSV-2 in less than one hour

Why send out? Identify and report same day results for HSV-1 and HSV-2

Alethia® HSV 1&2 provides actionable results to properly prescribe antiviral medications known to decrease risk of HSV-2 transmission by up to 50%.[3]

Nearly 50 million individuals in the U.S. are infected with HSV-2 and roughly one out of every six, ages 14-49 have genital herpes[2]. Of this group, 87% have not been clinically diagnosed.[1]

- HSV-1 and HSV-2 are closely related viruses which pose entirely different risks; therefore, it's critical to have a type-specific diagnosis to rule out suspected herpes blisters/sores.
- Alethia®'s molecular platform reduces your laboratory's turnaround time to report actionable results and eliminates the need for send-outs or viral culture testing.

Is your health system missing positives?

- How confident are you in your laboratory's current methodology for HSV testing?
- How well does your current test method differentiate between HSV-1 vs. HSV-2?

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SZABO SCANDIC

meridian BIOSCIENCE®
LIFE DISCOVERED. LIFE DIAGNOSED.

alethia®
HSV 1&2

Results That Matter

- Alethia® HSV 1&2 offers significant advantages over traditional viral culture by providing same day results from both cutaneous and mucocutaneous specimen types.
- Alethia® is a fast, accurate and reliable molecular solution that is easily adaptable in any laboratory with minimal hands-on time and no specialized training.

Improve Patient Outcomes

- Alethia® HSV 1&2 provides an actionable result to enable physicians to quickly start treatment of patients.
- The Alethia® HSV 1&2 is a sophisticated molecular test which can also help pediatricians educate families of newborn babies about the risks and dangers of HSV 1&2.

Product Specifications

Qualitative in vitro diagnostic test for the direct detection and differentiation of herpes simplex virus type 1 (HSV-1) and herpes simplex virus type 2 (HSV-2) DNA in cutaneous and mucocutaneous lesion specimens from male and female patients suspected of Herpetic lesions.

Turnaround Time

Less than one hour

Shelf Life

18 months

Sample Type

- Mucocutaneous — anorectal, genital — vaginal/ cervical, nasal, ocular, oral, urethral
- Cutaneous — skin, genital — penis

Sample Storage

- Samples should be stored refrigerated (2-8 C) after collection for up to 7 days and during transportation.

Kit Storage

Kit should be stored at 2-30C.

Performance

Cutaneous HSV-1:

94.1% Sensitivity **97.2%** Specificity

Cutaneous HSV-2:

100% Sensitivity **95.1%** Specificity

Mucocutaneous HSV-1:

95.0% Sensitivity **94.9%** Specificity

Mucocutaneous HSV-2:

98.6% Sensitivity **95.6%** Specificity

Catalog Number

Alethia® HSV 1&2 Test - 480650

Alethia® HSV 1&2
External Control Kit - 479960

CPT Codes

87529,
87529-59

References

1. Centers for Disease Control and Prevention. Genital Herpes — CDC Fact Sheet (Detailed). December 2014. http://www.cdc.gov/std/herpes/stdfact-herpes-detailed.htm
2. Centers for Disease Control and Prevention. Genital Herpes — CDC Fact Sheet. July 2014, http://www.cdc.gov/std/herpes/stdfact-herpes.htm
3. https://www.infectioncontroltoday.com/infections/antiviral-drug-found-reduce-genital-herpes-transmission-between-sexual-partners-50

Ready to get a handle on HSV testing? Let's talk.

Contact a specialist at **1-888-763-6769**.
meridianbioscience.com

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MBI_Alethia_HSV_SS_2020-01