

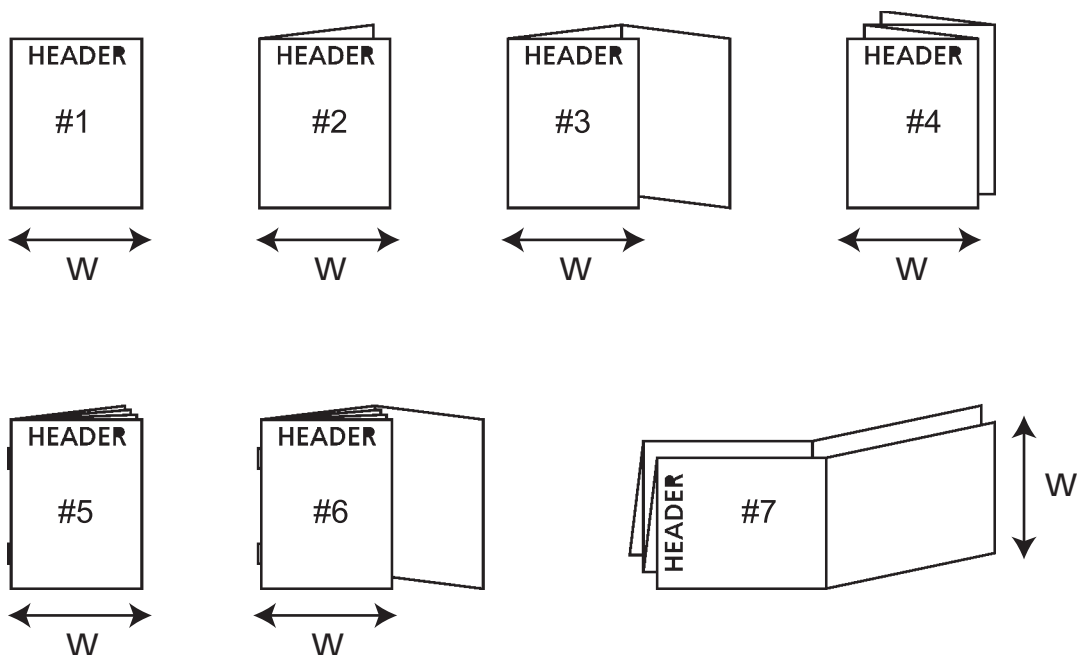
Revisions

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Inserts

Rev from	Rev to	JOB #
01	02	8509-16

NOTES:

- BD Catalog Number: 240915, 240916
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BD BBL™ Staphyloslide™ Latex Test Kit

**For Identification of *Staphylococcus aureus*
(for *in vitro* diagnostic use)**



L010794(02)

2016-06

INTENDED USE

The **BD BBL™ Staphyloslide™** Latex Test Kit provides a rapid platform for the identification of Staphylococcal isolates, particularly, *Staphylococcus aureus* which possess bound coagulase (clumping factor) and / or protein A from other species of staphylococci.

SUMMARY AND EXPLANATION

Although most *Staphylococcus* species are common inhabitants of the skin and mucous membranes, certain species have been found frequently as etiological agents of a variety of human and animal infections. Superficial suppurative infections caused by *S. aureus* are the most common human staphylococcal infections.¹ Food poisoning, septicemia, toxic shock syndrome and many other conditions also have been attributed to *S. aureus*.² Rapid slide agglutination tests have been shown to be a reliable method for the identification of *S. aureus* in the routine bacteriological laboratory.^{3,6}

PRINCIPLE OF THE TEST

The **BD BBL Staphyloslide** Latex Test Kit utilizes blue polystyrene latex particles that have been sensitized with fibrinogen and IgG. When Staphylococcal colonies which possess bound coagulase (clumping factor) and / or protein A are mixed with the latex reagent, the latex particles will agglutinate strongly within 20 seconds.

MATERIALS PROVIDED

- **BD BBL™ Staphyloslide™ Test Latex:** Two dropper bottles each containing 2.5 mL (100 tests/kit – Cat. No. 240915) or five dropper bottles each containing 5.0 mL (500 tests/kit – Cat. No. 240916) of latex particles coated with IgG and human fibrinogen. The latex particles are suspended in a buffer containing 0.098% sodium azide as a preservative.
- **BD BBL™ Staphyloslide™ Control Latex:** One dropper bottle containing 2.5 mL (Cat. No. 240915) or two dropper bottles containing 6.5 mL (Cat. No. 240916) of unsensitized latex particles suspended in a buffer containing 0.098% sodium azide as a preservative.
- Test cards
- Mixing sticks
- Instructions for use

MATERIALS REQUIRED BUT NOT PROVIDED

- Inoculating loop or needle
- Timer

STABILITY AND STORAGE

All kit components should be stored at 2 °C to 8 °C. Reagents stored under these conditions will be stable until the expiration date shown on the product labels.

Do not freeze.

PRECAUTIONS

1. Do not use the reagents after the expiration date shown on the product label.
2. The reagents contain a very small amount of sodium azide. Sodium azide can react explosively with copper or lead plumbing if allowed to accumulate. Although the amount of sodium azide in the reagents is minimal, large quantities of water should be used if the reagents are flushed down the sink.
3. Universal precautions should be taken in handling, processing and discarding all of the materials used to perform the test.
4. The kit is intended for *in vitro* diagnostic use only.
5. The procedures, storage conditions, precautions and limitations specified in these directions must be adhered to in order to obtain valid test results.
6. These reagents contain materials of human or animal origin and should be handled as a potential carrier and transmitter of disease.

PREPARATION OF CULTURES

For specific procedures regarding specimen collection and preparation of primary cultures refer to a standard microbiology textbook. In general, a fresh (18–24 hours incubation) isolate grown on non-selective media such as blood agar is preferred for testing. However, clinical studies have shown that this test will work if the isolate is taken from Chromogenic media. The user should always confirm that the test performs as expected if they are using a culture medium other than blood agar for the initial culture of the specimen.

TEST PROTOCOL

1. Remove the test kit from the refrigerator 10 minutes prior to use and allow the latex reagents to reach room temperature.
2. Resuspend the latex reagent by inverting the dropper bottle several times.
3. Dispense 1 drop of **BD BBL Staphyloslide** Test Latex into a circle on the test card.

- Using a sterile loop or needle, transfer two colonies of the test isolate into the circle. Mix this into the test latex reagent and spread to cover the complete area of the circle.
- Gently rock the card allowing the mixture to flow slowly over the entire test ring area.
- Observe for agglutination for up to 20 seconds.
- BD BBL Staphyloslide** Control Latex is included in the kit to be used in accordance with the customer's requirements.

QUALITY CONTROL PROCEDURES

The following procedures are recommended to check the performance of the reagents:

- Test a known positive strain such as *S. aureus* ATCC® # 25923 or equivalent according to the test protocol. The organism must agglutinate with the **BD BBL Staphyloslide** Test Latex within 20 seconds. There must be no agglutination with the **BD BBL Staphyloslide** Control Latex.
- Test a known negative strain such as *S. epidermidis* ATCC # 12228 or equivalent according to the test protocol. There must be no agglutination of the **BD BBL Staphyloslide** Test Latex and **BD BBL Staphyloslide** Control Latex within 20 seconds.
- Do not use the kit if the reactions with the control organisms are incorrect.

INTERPRETATION OF RESULTS

- Positive result:** Strong agglutination within 20 seconds with the Staph Test Latex Reagent. If you have performed a negative control there should be no agglutination with the Negative Control Latex Reagent. Clumping occurring after the 20 seconds should be ignored.
- Negative result:** No visible agglutination of the Staph Test Latex Reagent particles.
- Inconclusive result:** If weak clumping or a non-specific reaction (stringiness) is present in the test circle after 20 seconds, the test should be repeated using a fresh subculture. If the same result is seen after retesting, biochemical testing should be used to identify the isolate.
- Uninterpretable result:** If the test isolate agglutinates with both the **BD BBL Staphyloslide** Latex and Negative Control Latex, the test is uninterpretable.

LIMITATIONS OF THE PROCEDURE

1. False negative or false positive results can occur if inadequate amounts of culture or reagent are used.
2. Some rare isolates of staphylococci, notably *S. hyicus* and *S. intermedius*, may agglutinate the latex reagent.⁴
3. Some streptococci and possibly other organisms that possess immunoglobulin binding factors and some species such as *Escherichia coli* may also agglutinate latex reagents non-specifically.⁵

PERFORMANCE CHARACTERISTICS

The **BD BBL™ Staphyloslide™** Latex Test Kit (Cat. Nos. 240915/240916) was evaluated in the Clinical Microbiology Department of a hospital in the United Kingdom. A total of 100 known strains were tested (50 MSSA, 30 MRSA and 20 CNS). Strains were grown on Chromogenic agar. Coagulase and DNase testing was used to confirm *Staphylococcus*, and methicillin strips on nutrient agar was used to confirm MRSA. CNS were identified by multipoint or API. Cat. Nos. 240915/240916 correctly identified all *Staphylococcus aureus* strains as positive and all CNS gave a negative result. In this study, the **BD BBL Staphyloslide** Latex Test Kit was found to have a sensitivity of 100% and specificity of 100%.

AVAILABILITY

Cat No.	Description
240915	BD BBL™ Staphyloslide™ Latex Test Kit, 100 Tests.
240916	BD BBL™ Staphyloslide™ Latex Test Kit, 500 Tests.

REFERENCES

1. Schleifer, K.H., and Kloos, W.E. (1975). Int. J. Syst. Bacteriol. 25: 50–61.
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5. Myhre, E.B. and Kuusela, P. (1983). Inf. Imm. 40: 29–34.
6. Berke, A. and Tilton, R.C. (1986). J. Clin. Microbiol. 23: 916–919.

Technical Information: In the United States, contact BD Technical Service and Support at 1.800.638.8663 or www.bd.com.



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 ГГГГ-ММ-ДД / ГГГГ-ММ (ММ = края на месеца)
 RRRR-MM-DD / RRRR-MM (MM = koniec miesiąca)
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 JJJJ-MM-TT / JJJJ-MM (MM = Monatsende)
 EEEE-MM-HH / EEEE-MM (MM = τέλος του μήνα)
 AAAA-MM-DD / AAAA-MM (MM = fin del mes)
 AAAA-KK-PP / AAAA-KK (KK = kuu lõpp)
 AAAA-MM-JJ / AAAA-MM (MM = fin du mois)
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 YYYY-MM-DD/YYYY-MM (MM = 월말)
 MMMM-MM-DD / MMMM-MM (MM = mēnesio pabaiga)
 GGGG-MM-DD/GGGG-MM (MM = mēneša beigas)
 JJJJ-MM-DD / JJJJ-MM (MM = einde maand)
 AAAA-MM-DD / AAAA-MM (MM = slutten av månaden)
 RRRR-MM-DD / RRRR-MM (MM = koniec miesiąca)
 AAAA-MM-DD / AAAA-MM (MM = fim do mês)
 AAAA-LL-ZZ / AAAA-LL (LL = sfârșitul lunii)
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 RRRR-MM-DD / RRRR-MM (MM = koniec miesiąca)
 GGGG-MM-DD / GGGG-MM (MM = kraj meseca)
 AAAA-MM-DD / AAAA-MM (MM = slutet av månaden)
 YYYY-AA-GG / YYYY-AA (AA = ayın sonu)
 PPPP-MM-DD / PPPP-MM (MM = кінець місяця)
 YYYY-MM-DD / YYYY-MM (MM = 月末)



Catalog number / Каталоген номер / Katalogové číslo / Katalognummer / Αριθμός καταλόγου / Número de catálogo / Katalooginumbr / Numéro catalogue / Kataloški broj / Katalógusszám / Numero di catalogo / Каталог номер / 카탈로그 번호 / Katalogo / numeris / Kataloga numurs / Catalogus nummer / Numer katalogowy / Număr de catalog / Номер по каталогу / Katalogové číslo / Kataloški broj / Katalog numarası / Номер за каталогом / 目录号



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