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# **Amplified IDEIA Hp StAR**

# INTENDED USE

The Amplified IDEIA<sup>™</sup> Hp StAR<sup>™</sup> test is an in vitro qualitative enzyme immunoassay for the detection of Helicobacter pylori antigens in human stool samples. Test results are intended to aid the diagnosis of *Helicobacter pylori* infection and to monitor response post-therapy in adult patients and children.

**IVD** - For *in vitro* diagnostic use. For professional use only. Anyone performing an assay with this product must be trained in its use and must be experienced in laboratory procedures.

#### 2. SUMMARY

In 1984 Marshall and Warren described the presence of a Campylobacter-like organism in the antrum and corpus of patients with histological evidence of gastritis and peptic ulcers<sup>1</sup>. Today H. pylori is well recognized as a major cause of gastrointestinal diseases<sup>2</sup>.

Infection by H. pylori leads to inflammation, which has a strong correlation with chronic gastritis, ulcers of the stomach and the duodenum, and gastric carcinoma<sup>3, 4</sup>. Patients with successful eradication therapy show evidence for this cause and effect relationship - often gastritis and ulcers are cured.

These bacteria have adapted to live in the acidic environment of the stomach. The enzyme urease cleaves urea into ammonia and carbon dioxide, thus neutralizing the acid and enabling H. pylori to survive the bactericidal conditions of the stomach. The production of catalase and superoxide dismutase protects the bacteria from neutrophilic attack in the stomach mucosa<sup>3</sup>

Many H. pylori infected patients develop gastritis, and about 10% of them ulcers. 90% of patients suffering from ulcers of the duodenum or the stomach are H. pylori positive, regardless of age. The reasons for these phenomena as well as the way of infection are subject to worldwide research<sup>5</sup>.

There are two general methods of diagnosing H. pylori infection: the direct detection of the organism and the indirect determination by the detection of antibodies developed by the patient again H. pylori 1, 6, 7

Direct, but invasive methods to detect H. pylori infection are the rapid urease test, histology or the culture of the organism from the biopsy material8. Culturing of H. pylori from biopsy material is difficult and time consuming. The technical difficulties can lead to false negative results and therefore to a reduced sensitivity. In addition, H. pylori tends to colonize the mucosa in patches and can therefore be missed during endoscopy<sup>9</sup>.

Another direct way of diagnosing *H. pylori* is the use of an urea breath test, which detects carbon dioxide produced by the urease activity. Although highly sensitive and specific, it requires specialized instrumentation as well as the ingestion of isotope-labeled urea by the patient<sup>8, 10</sup>

A commonly used method is the serological detection of antibodies specific for *H. pylori*. This is an indirect approach detecting H. pylori specific antibodies developed by the patient10. Sensitivity and specificity vary greatly among tests from different suppliers. Furthermore, eradication control with serological methods is insufficient, because a significant decrease of antibody level takes several months.

Amplified IDEIA Hp StAR test is a sandwich-type enzyme immunoassay (EIA) in a microplate format for the direct, noninvasive detection of *H. pylori* antigens in human faeces. Due to the direct detection of antigens this test can be used for the initial diagnosis of *H. pylori* infection as well as for monitoring eradication success four to six weeks after completion of eradication therapy and also for the diagnosis of reinfection.

# PRINCIPLE OF THE TEST

Amplified IDEIA Hp StAR test is a sandwich-type enzyme immunoassay using immunoassay amplification technology for the determination of H. pylori antigens in faeces.

The wells of the microplate are coated with monoclonal antibodies specific for *H. pylori* antigens.

Supernatant of a faecal suspension as well as horseradish

Ready to use. Store unused substrate at 2-8°C. Protect from light. 6.8

Ready to use. Store unused stop solution at 2-8°C ADDITIONAL REAGENTS

Fresh deionised or distilled water for preparation of working strength wash buffer.

# EQUIPMENT

Substrate

Stop Solution

The following equipment is required:

Test tubes.

Vortex mixer

Distilled or deionized water.

Clean absorbent paper (onto which microwells can be tapped dry).

Precision micropipettes and disposable tips to deliver  $50\mu$ L, 100µL and 500µL volumes (optional).

Bench top centrifuge (minimum 5000 rpm).

Microtitration plate shaker capable of a minimum speed of 500 rpm with an orbital diameter of 1-3mm. For information on suitability of plate shakers contact your local Oxoid subsidiary or distributor.

Automated plate washer (optional) or suitable equipment for washing 8 microwell strips (See Section 11.2.4). Note: If washing less than 8 test microwells in a strip using an automated washer with an 8 microwell head, it is important to completely fill the strip with blank microwells

Spectrophotometer or EIA plate reader able to read a 96 microwell plate of 8 microwell strips at an absorbance of 450nm with a reference at 620-650nm. (Section 11.3, Reading the Test Results).

#### WARNINGS, PRECAUTIONS & MEASURES 9.

#### 9.1. SAFETY PRECAUTIONS

- 9.1.1 Stop solution contains sulphuric acid (0.5mol/L). Avoid eye and skin contact by wearing protective clothing and eye protection.
- 9.1.2 Reagents of this kit contain antimicrobial agents and the Substrate Solution contains Tetramethylbenzidine. Avoid contact with skin and eyes. Rinse immediately with plenty of water if any contact occurs.
- 9.1.3 Do not eat, drink, smoke, store or prepare foods, or apply cosmetics within the designated work area.
- Do not pipette materials by mouth. 9.1.4
- Wear disposable gloves while handling clinical 9.1.5 specimens and reagents. Always wash hands after working with infectious materials.
- Dispose of all clinical specimens in accordance with 9.1.6 local legislation.
- Safety data sheet available for professional user on 9.1.7 request

#### **TECHNICAL PRECAUTIONS** 9.2.

- 9.2.1 Components must not be used after the expiry date printed on the labels. Do not mix or interchange different batches/lots of reagents.
- DO NOT freeze any kit components. 9.2.2
- 9.2.3 The reagents are provided at fixed working concentrations. Test performance will be affected if reagents are modified or stored under conditions other than those detailed in Section 6.
- 9.2.4 Controls are intended to monitor for substantial reagent failure. The Positive Control will not ensure precision at the cut-off.
- 9.2.5 Kit components should be examined visually for signs of contamination, deterioration or leakage. Substrate Solution must not be used if turned blue.
  - If the Negative Control yields absorbance values > 0.10 (450/620-650nm), or >0.14 (450nm) this may indicate insufficient washing. It is recommended to wash the strips more intensively when repeating the test.
- 9.2.7 Avoid contamination of reagents.
- 9.2.8 Use separate disposable pipettes or pipette tips for each specimen, control or reagent in order to avoid cross contamination of either specimens, controls or reagents which could cause erroneous results.
- 9.2.9 Store deionised or distilled water for dilution of concentrated reagent in clean containers to prevent microbial contamination.
- 9.2.10 Avoid contamination with metal ions and oxidising agents.
- 9.2.11 Protect Substrate from light.

suspension for 5 minutes at 5000 rpm (2500g)

Stool suspension may be stored for 24 hours at 2-8°C but not frozen

#### TEST PROCEDURE 11.

PLEASE REFER TO SECTION 9.2, TECHNICAL PRECAUTIONS, BEFORE PERFORMING THE TEST PROCEDURE.

Reagents and specimens should be brought to room temperature (15 30°C) before use.

# 11.1. PREPARATION OF CONTROLS

Mix gently before use.

At least one Amplified IDEIA Hp StAR negative and one positive control must be included with each batch of specimens tested (see Section 11.2.1).

11.2. ASSAY PROCEDURE

### 11.2.1 Specimen Addition

Pipette 50µl of the stool supernatant, 50µl of the Positive Control and  $50\mu l$  of the Negative Control into separate microwells.

Avoid disturbing or sampling any sediment in the vial. When dispensing specimens, hold the transfer pipette vertically with the tip immediately above the microwell and ensure that the specimen is delivered without touching the sides of the microwell. Take care not to cross-contaminate specimen and control microwells as this may cause erroneous results.

# 11.2.2 Conjugate Addition

Add 50µl of the ready to use Conjugate directly to each microwell.

### 11.2.3 First Incubation

Cover the microplate with the sealer provided. Incubate at 18-27°C with shaking for 60 ± 5 minutes.

### 11.2.4 Washing the Microwells

The washing technique is critical to the test performance (see Section 9.2.12) and should be carried out so as to ensure complete filling (with a minimum of 250-300µL of working strength wash buffer) and emptying of the microwells.

Five wash cycles are essential, by either automated or manual washing techniques.

Carefully remove plate sealer before washing.

# Manual Washing

If washing microwells manually, aspirate or shake out the contents of the microwells and using freshly prepared wash buffer, ensure complete filling and emptying of microwells. Between each wash step remove all remaining wash buffer by tapping the inverted microwells on to clean absorbent paper. Manual washing efficiency is further ensured if the wash buffer is delivered at an angle so as to produce a vortex in the microwells. After the final wash, the plate should be inverted and tapped on absorbent paper to remove the last traces of wash buffer.

### Automated Washing

Automated washers should be programmed to complete 5 wash cycles. Washers must be correctly calibrated to ensure complete filling and emptying of microwells between each wash. After the final wash, the plate should be inverted and tapped on absorbent paper to remove the last traces of wash buffer.

### 11.2.5 Substrate Addition

Add 100µL of substrate to each microwell

11.2.6 Second Incubation

Incubate at 20-30°C for 10 minutes.

11.2.7 Stopping the Reaction

Stop the reaction by adding 100µl Stop Solution.

11.3. READING THE TEST RESULTS

### 11.3.1 Photometric Reading

The microwells should be read photometrically within 15 minutes of the stop solution addition. Mix the contents of the microwells and read the absorbance of each microwell using a suitable spectrophotometer or EIA plate reader set at 450nm. Ensure that the bottoms of the microwells are clean before reading and check that no foreign matter is present in the microwells. The reader should be blanked on air (ie with no plate in the carriage) before the plate is scanned.

Alternatively, if the spectrophotometer or EIA plate reader allows for the use of a reference wavelength (at 620 to 650nm), dual wavelength reading should be performed which will eliminate any potential interference caused by aberrations, such as dirt or marks, on the optical surface of the microwells

# 11.4. SUMMARY OF THE AMPLIFIED IDEIA™ Hp StAR™ ASSAY PROCEDURE

Ensure all reagents reach room temperature (15-30°C) before use



SUBSTRATE TMB

STOP SOLUTION

6.1



### SYMBOL LEGEND

Δ

4. STRIBOL LEGEND			
CONTROL +	Positive Control		
CONTROL -	Negative Control		
REF	Catalogue Number		
IVD	In Vitro Diagnostic Medical Device		
i	Consult Instructions for Use (IFU)		
J.	Temperature Limitations (Storage temp.)		
类	Keep away from sunlight		
Σ <sub>N</sub>	Contains sufficient for <n> tests</n>		
LOT	Batch Code (Lot Number)		
	Use By (Expiration Date)		
EC REP	Authorized representative in the European Community		
	Manufacturer		
5. REAGE	ENTS PROVIDED		

i

MICROTITRATION PLATE

SAMPLE DILUENT

CONTROL +

Each kit contains sufficient materials for 96 determinations. The shelf life of the kit is as indicated on the outer box label. Store unused components at 2-8°C.

Instructions for Use.

100 x Wooden Sticks.

One bottle of each of the following unless indicated otherwise:

microwells.

agents.

1 x Microplate Strip Sealer.

One 96 well microtitration plate of twelve,

8 microwell break-apart strips coated with

monoclonal antibodies specific for H. pylori

antigens. A resealable foil pouch containing

a desicant is provided for storage of unused

55mL sample diluent: 75mM phosphate

buffered solution, pH 7.4 with antimicrobial

2mL positive control: inactivated

fractionated H. pylori lysate in 75mM

phosphate buffered, red coloured solution,

12mL substrate: aqueous solution of TMB

12mL stop solution: 0.5mol/L sulphuric

### AMPLIFIED IDEIA Hp StAR TEST CONTENTS

peroxidase (HRP) labelled monoclonal antibodies (Antibody Conjugate) are added to the wells in one step. During incubation, H. pylori antigens present in a sample bind to the antibodies on the microplate and to the HRP labelled antibodies thus forming a 'sandwich complex'.

The wells are washed in order to remove unbound Antibody Conjugate. A colourless single-component enzyme substrate (Tetramethylbenzidine – TMB) is added. Bound HRP oxidizes TMB to a blue coloured product. By adding the Stop Solution the colour changes to yellow. The intensity of the colour is determined spectrophotometrically.

#### PREPARATION, STORAGE AND RE-USE OF KIT 6. COMPONENTS

and hydrogen peroxide.

In order to ensure optimal kit performance it is important 9.2.13 that all unused kit components are stored according to the following instructions.

### Antibody Coated Microwells

agents.

acid.

Open the plate pouch with scissors without detaching the fastener. Break off the required number of microwells and relocate them into the frame. Return all unused microwells and strips to the resealable foil pouch with the desiccant. Carefully reseal the pouch and store at 2-8°C.

#### 6.2 Sample Diluent

Ready to use. Store unused sample diluent at 2-8°C.

#### 6.3 Positive Control

Ready to use. Store unused positive control at 2-8°C.

#### **Negative Control** 6.4

Ready to use. Store unused negative control at 2-8°C.

#### Conjugate 6.5

Ready to use. Store unused conjugate at 2-8°C.

#### Wash Buffer Concentrate 6.6

Provided x10 concentrate. Prepare working strength wash buffer by adding 1 part of wash buffer concentrate to 9 parts fresh deionised or distilled water. The diluted wash buffer has a shelf life of 3 months if stored in a closed bottle at 2-8°C. The concentrated wash buffer may show a slight precipitate. Bring to room temperature and mix gently to dissolve the precipitate before use. Store unused concentrate at 2-8°C.

9.2.12 Do not use substrate showing a blue colour prior to its addition to the microwells.

Microwells cannot be re used.

- Manual or automated washing equipment must 9.2.14 be free of microbial contamination, be correctly calibrated and maintained according to the manufacturer's instructions.
- COLLECTION AND PREPARATION OF FAECAL 10. SPECIMENS

# 10.1. SPECIMEN COLLECTION

The test can be performed on either fresh or frozen faeces. Fresh samples may be transported at ambient temperature for two days. Upon arrival in the laboratory the samples should be stored at -20°C or below.

Alternatively, the samples may be stored at 2-8°C for up to three days without interference with the assay performance. Repeated freezing and thawing of samples should be avoided.

Samples collected into transport medium or other preservative media should not be tested

# 10.2. PREPARATION OF FAECAL SPECIMENS

Pipette 500 $\mu l$  of the Sample Diluent into a properly marked tube. Mix the stool sample. Using a wooden stick applicator add a pea-sized stool sample (approximately 0.1g) to the Sample Diluent. For liquid stool samples 100µl stool should be used. Homogenize for 15 seconds on a vortex mixer. Use a new wooden stick applicator for each sample. Centrifuge the



#### INTERPRETATION OF THE TEST RESULTS 12.

12.1. POSITIVE CONTROL AND NEGATIVE CONTROL As detailed in Section 11.1 (Preparation of Controls) at least one negative and one positive control must be included in each assay run.

The following quality criteria should be met:

Positive Control	OD <sub>450 / 620 to 650nm</sub>	> 1.00 (OD <sub>450nm</sub> > 1.04)
Negative Control	OD <sub>450 / 620 to 650nm</sub>	< 0.10 (OD <sub>450nm</sub> < 0.14)

12.2. SPECIMENS

### Test results are interpreted as follows:

Dual wavelength (450/620 to 650nm)

Specimens with absorbance values  $\geq 0.150$  are positive.

# Specimens with absorbance values < 0.150 are negative.

# Single wavelength (450nm)

If it is not possible to use a reference wavelength between 620 and 650nm on the microplate reader, the cut-off is as follows:

Specimens with absorbance values  $\geq$  **0.190** are positive.

Specimens with absorbance values < 0.190 are negative.

A positive test result indicates the presence of H. pylori antigens. A negative result indicates the absence of *H. pylori* antigens or a concentration of antigens below the detection limit.

If, after the addition of substrate, the content of a microwell turns dark blue and forms a blue-black precipitate, the specimen should be interpreted as positive.

#### PERFORMANCE LIMITATIONS 13.

- 13.1. Amplified IDEIA Hp StAR is a gualitative test and no quantitative interpretation should be made. Test results should be interpreted by the clinician in conjunction with clinical findings and/or other diagnostic procedures
- 13.2. Antibiotics, proton pump inhibitors and bismuth preparations are known to suppress growth of H. pylori. Stool sampling must be performed not earlier than 2 weeks after termination of ingestion of proton pump inhibitors and bismuth preparations and 4 weeks after termination of ingestion of antibiotics, respectively
- 13.3. A negative result does not exclude the possiblity of *H. pylori* infection in the patient. Failure to detect H. pylori may be a result of factors such as improper sampling or handling of the specimen.
- 13.4. A positive test result alone does not justify an indication for eradication therapy. Other methods may be nessecary to confirm H. pylori infection. Differential diagnosis with invasive endoscopic methods might be indicated in order to examine the presence of any other complicating conditions, eg ulcer, autoimmune gastritis and malignancies.
- 13.5. A test result within 0.020 absorbance units around the cut-off value should be interpreted with caution.

#### EXPECTED VALUES 14.

Expected values depend on geographic location and type of population studied. The rate of positive test results may vary due to the type of test employed and the method of specimen collecti0on and handling.

Epidemiological studies have shown that the infection by H. pylori is prevalent throughout the world. In Europe and North America 25-50% of the population carries H. pylori. Even higher prevalence rates of 70-90% have been reported for Asia, Africa and South America<sup>1, 11</sup>

The frequency of *H. pylori* infection has been shown to correlate with age, ethnic background, socioeconomic class and the general health environment eg the prevalence of infection in the United States increases with age at approximately 1% per year<sup>12</sup>.

#### 15. SPECIFIC PERFORMANCE CHARACTERISTICS

### 15.1. CLINICAL STUDIES

Study 1: Primary diagnosis in adult patients

Amplified IDEIA Hp StAR test was evaluated on 356 patients (201 female, 155 male, age range 18 - 82 years) from 10 centers in Germany undergoing endoscopy because of abdominal pain and dyspepsia. Stool testing was performed in independent laboratories in a blinded fashion.

The patients had a variety of gastric pathologies noted. including: mild gastritis (n=61), chemical toxic gastritis (n=98), H. pylori associated gastritis (n=144), antral erosions (n=11), atrophic gastritis (n=2), gastric ulcer (n=5), duodenal ulcer (n=3), adenocarcinoma (n=2), submucous tumor (n=1) Schatzki's Ring (n=1), Crohn gastritis (n=1), asymptomatic (n=27).

Amplified IDEIA Hp StAR test results were compared to

Table 2: Primary diagnosis in pediatric patients using Amplified IDEIA Hp StAR and the reference tests histology/ 4. culture

	Histology		Sensitivity	98.6% (70/71)
Hp StAR	Culture		± 95% Cl	92.4 - 100%
	+	-		
+	70	1	Specificity	99.4% (167/168)
-	1	167	+ 95%	96.7 - 100%

### Study 3: Monitoring the response to eradication therapy in paediatric patients

40 H. pylori infected children (age 3 to 15 years) with recurrent abdominal pain were recruited in two pediatric gastroenterology centers 13. H. pylori infection was shown by urea breath test and serology. All 40 faecal samples were identified positive by Amplified IDEIA Hp StAR. Eradication was performed by triple therapy for seven days. Eradication control was performed by urea breath test four weeks after therapy. Amplified IDEIA Hp StAR showed a sensitivity of 100% and a specificity of 96.9%. Confidence intervals (CI) were calculated using the exact binomial method. Results are shown in table 3.

## Table 3: Performance of Amplified IDEIA Hp StAR relative 9. to UBT for monitorng response to eradication therapy in paediatric patients.

Hp StAR	Urea breath test		Sensitivity ± 95% Cl	100% (8/8) 63.1 – 100%
	+	-		
+	8	1	Specificity	96.9% (31/32)
-	0	31	± 95%	83.8 - 99.9%

# Study 4: Monitoring the response to eradication therapy in adult patients

Stool samples were collected from 93 patients in the North East of Spain (64 male and 29 female, age range 21 - 80 years) who had undergone eradication therapy for confirmed H. pylori infection. Patients were instructed to obtain a faecal sample the same day that the UBT for controlling eradication therapy was performed (at least 4 weeks post completion of therapy). Samples were immediately frozen and kept at -80°C then thawed and tested with Amplified IDEIA Hp StAR.

Table 4 shows the results obtained with Amplified IDEIA Hp StAR when compared with the reference method (UBT). Amplified IDEIA Hp StAR demonstrated sensitivity and specificity of 80% (8/10) and 97.6% (81/83) respectively and an overall correlation of 95.7% (89/93) relative to UBT.

### Table 4: Performance of Amplified IDEIA Hp StAR relative to UBT for monitoring response to eradication therapy in adult patients

Hp StAR	Urea breath test		Sensitivity ± 95% Cl	80% (8/10) 44.4 – 97.5%
	+	-		
+	8	2	Specificity	97.6% (81/83)
-	2	81	± 95% Cl	91.6 - 99.7%

### 15.2. REPRODUCIBILITY

Intra-assay and inter-assay variations were determined by testing weak positive (n=2), medium positive (n=2) and strong positive (n=2) as well as negative samples (n=2). Reproducibility testing was performed in three independent laboratories in Europe. Each sample was tested in 10 wells at each site. Intra-assay and inter-assay coefficients of variations (CV) were calculated and are presented below. Ranges for OD-values and intra- and inter-assay variances are given for the different stool samples tested.

Table 5: Intra- and inter-assay variation of Amplified **IDEIA Hp StAR** 

	Negative samples	Weak positive samples	Medium positive samples	Strong positive samples
OD 450/630nm	0.024 – 0.070	0.495–0.897	1.306 - 2.656	3.00 - 3.77
Intra-assay CV	5.9 – 17.4%	2.7 – 10.1%	2.1 - 4.0%	1.1 - 3.1%
Intra-assay CV	41.2-46.1%	23.0 – 25.8%	24.1 - 25.4%	8.1 - 10.2%

#### **CROSS REACTIVITY** 16.

Amplified IDEIA Hp StAR stool assay is highly specific for antigens from H. pylori. For each strain a concentration of  $\geq$  1×10<sup>8</sup> organisms/ml in sample buffer was tested. No cross reactivity was observed when testing the microorganisms listed below. In contrast *H. pylori* gave a positive test result.

Acinetobacter lwoffii Providencia stuartii

Pseudomonas aeruginosa

Gastroenterology 14 (suppl. 1): 15-19.

Delchier, J.-C., Ebert, M., Malfertheiner, P. (1998). Helicobacter pylori in gastric lymphoma and carcinoma. Current Opinion in Gastroenterology 14 (suppl. 1): 41-45

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the diagnosis of H. pylori infection as judged by histology. Amplified IDEIA<sup>™</sup> Hp StAR<sup>™</sup> showed a sensitivity of 95.3% and a specificity of 97.1%. Confidence intervals (CI) were calculated using the exact binomial method. Results are shown in table 1.

#### Table 1: Primary diagnosis in adult patients using Amplified **IDEIA Hp StAR** and the reference test histology

	Histology		Sensitivity	95.3% (141/148)
Hp StAR			± 95% Cl	90.5 - 98.1%
	+	-		
+	141	6	Specificity	97.1% (202/208)
-	7	202	± 95%	93.8 -98.9%

### Study 2: Primary diagnosis in pediatric patients

Amplified IDEIA Hp StAR assay was tested in a study performed with faecal samples from children undergoing endoscopy because of abdominal pain and/or other intestinal disorders. 239 children (124 male, 115 female, age range 6 months to 18 years) from three pediatric gastroenterology centers in Europe were included.

As reference tests histology and culture were used. The 2. patient was defined H. pylori positive if histology and/or culture were positive and H. pylori negative if both tests were negative. Amplified IDEIA Hp StAR showed a sensitivity of 98.6% and a specificity of 99.4%. Confidence intervals (CI) were calculated using the exact binomial method.

Aeromonas hydrophila hydrophila

Aeromonas hydrophila

anaerogenes

Campylobacter fetus Campylobacter jejuni Citrobacter freundii

Enterobacter cloacae Enterococcus faecalis

Enterococcus faecium
Escherichia coli
Escherichia hermannii
Lactoccocus lactis
Listeria innocua
Proteus mirabilis
Proteus vulgaris

1.

3.

Pseudomonas fluorescens Pseudomonas putida Salmonella agona Salmonella choleraesuis Salmonella infantis Salmonella ohio Salmonella typhimurium Serratia proteamaculans Shigella flexneri Shigella sonnei Staphylococcus aureus Streptococcus agalactiae Streptococcus dysgalactiae

#### 17. **REFERENCES/LITERATURE**

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