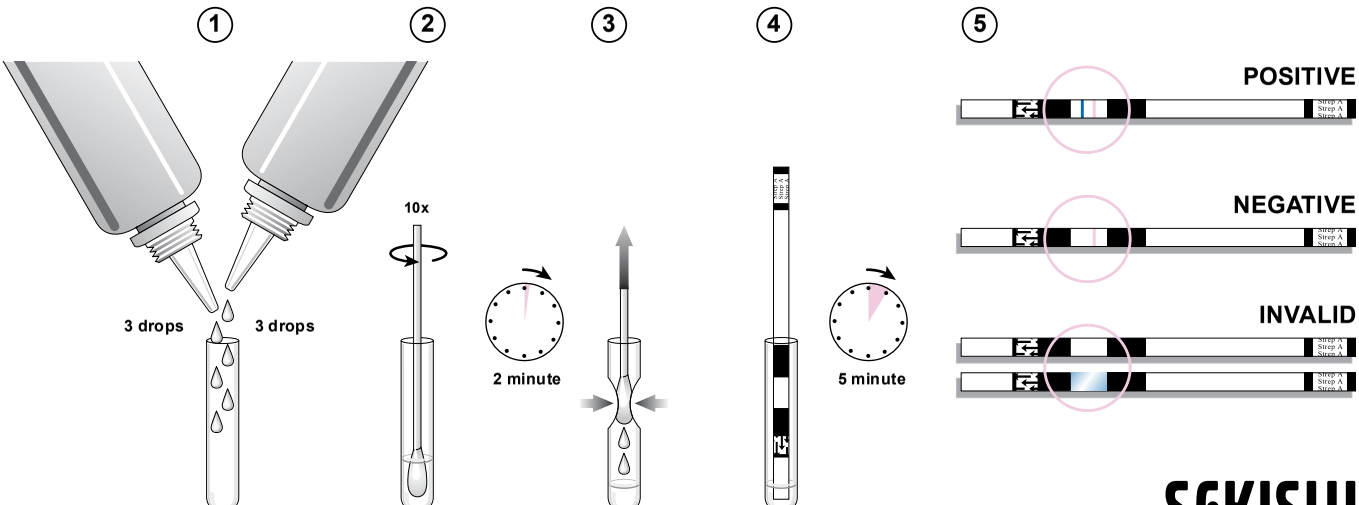
osom® Ultra Strep A Test



SEKISUI DIAGNOSTICS

OSOM® Ultra Strep A Test

CLIA Complexity: Waived

℞ ONLY

INTENDED USE

The OSOM® Ultra Strep A Test is a color immunochromatographic assay intended for the qualitative detection of Group A Streptococcal antigen directly from throat swab specimens. For laboratory and professional *in vitro* diagnostic use only.

SUMMARY AND EXPLANATION OF TEST

Group A Streptococcus is one of the most important causes of acute upper respiratory tract infection. Early diagnosis and treatment of Group A Streptococcal pharyngitis has been shown to reduce the severity of symptoms and further complications such as rheumatic fever and glomerulonephritis.[1] Conventional identification procedures for Group A Streptococcus from throat swabs involve the isolation and subsequent identification of viable pathogens by techniques that require 18 to 24 hours or longer.[2] The OSOM Ultra Strep A Test detects either viable or nonviable organisms directly from a throat swab, providing results within 7 minutes.

PRINCIPLES OF TEST

The OSOM Ultra Strep A Test is a color immunochromatographic assay using Dual Label Technology (DLT)**. DLT uses antibody labeled color particles coated at two separate locations in the test device. DLT allows greater sensitivity than the conventional single label technology without sacrificing specificity. In the test procedure, a throat swab is subjected to a chemical extraction of a carbohydrate antigen unique to Group A Streptococcus. The Test Stick is then placed in the extraction mixture and the mixture migrates along the membrane. If Group A Streptococcus is present in the sample, it will form complexes with the anti-Group A Streptococcus antibody conjugated color particles located at two separate locations on the Test Stick. The complex will then be bound by the anti-Group A Streptococcus capture antibody and a visible blue Test Line will appear to indicate a positive result. A red Control Line will also appear to indicate the test is valid.

KIT CONTENTS AND STORAGE

50 - Test Sticks Coated with Rabbit Anti-Group A Streptococcus
50 - Test Tubes
50 - Sterile Swabs
1 - Reagent A (2 M Sodium Nitrite). Caution: Harmful if swallowed
1 - Reagent B (0.3 M Acetic Acid). Warning: Severe eye irritant
1 - Positive Control (Nonviable Group A Streptococci, 0.1% Sodium Azide)
1 - Negative Control (Nonviable Group C Streptococci, 0.1% Sodium Azide)
1 - Workstation
1 - Directional Insert

NOTE: Two extra test sticks have been included in the kit for external QC testing.
In addition, extra components (swabs, tubes) have been provided for your convenience.

- Store Test Sticks and reagents tightly capped at 15°–30°C (59°–86°F).
- Do not use Test Sticks or reagents after expiration date.

MATERIALS REQUIRED BUT NOT PROVIDED

A timer or watch.

WARNINGS AND PRECAUTIONS

Component (s)	Pictogram	Signal Word	Hazardous Ingredients
Ultra Strep A REAG A		Warning	sodium nitrite (CAS No) 7632-00-0
Hazard statements	H302 - Harmful if swallowed		
Precautionary statements	P264 - Wash hands, forearms and face thoroughly after handling. P270 - Do not eat, drink or smoke when using this product. P301+P312 - If swallowed: Call a poison center or doctor if you feel unwell. P330 - Rinse mouth. P501 - Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.		

Ultra Strep A REAG B		Warning	Acetic acid (CAS No) 64-19-7
Hazard statements	H315 - Causes skin irritation H319 - Causes serious eye irritation		
Precautionary statements	P264 - Wash hands, forearms and face thoroughly after handling. P280 - Wear protective gloves/protective clothing/eye protection/face protection. P302+P352 - If on skin: Wash with plenty of water. P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P321 - Specific treatment (see supplemental first aid instruction on this label). P332+P313 - If skin irritation occurs: Get medical advice/attention. P337+P313 - If eye irritation persists: Get medical advice/attention. P362+P364 - Take off contaminated clothing and wash it before reuse.		

- For *in vitro* diagnostic use.
- **Caution:** Federal Law restricts this device to sale by or on the order of a licensed practitioner.
- Follow your laboratory safety guidelines in the collection, handling, storage and disposal of controls, patient specimens and all items exposed to patient specimens[3].
- The Positive and Negative Controls contain sodium azide which may react with lead or copper plumbing to form potentially explosive metal azide. For sites permitted to dispose of material down the sink: large quantities of water must be used to flush discarded control material down a sink.
- Do not interchange or mix components from different kit lots.

SPECIMEN COLLECTION AND PREPARATION

- Collect specimens with a sterile swab from the tonsils and/or the back of the throat[2] taking care to avoid the teeth, gums, tongue or cheek surfaces.
  - Do not use swabs with cotton tips, wooden shafts or calcium alginate swabs.
  - Do not use a collection system that contains charcoal or semisolid transport media.
- If your lab requires a culture result as well as the OSOM Ultra Strep A Test result, streak the culture plate with the swab before starting the OSOM Ultra Strep A Test procedure as the extraction reagents will cause the specimen to become nonviable.
- Process the swab as soon as possible after collecting the specimen. If you do not perform the OSOM Ultra Strep A test immediately, store the swabs either at room temperature or refrigerated for up to 48 hours. The swabs and the test kit must be at room temperature prior to running the test.
- Sample Transport:
  - Because the performance characteristics of this product were established with the sterile rayon swabs supplied with the kit, we recommend using these swabs to assure optimal performance. You may purchase the kit swabs in a double swab/dry tube format as an accessory (SEKISUI Diagnostics Catalog #7784).
  - Because the test does not require live organisms for processing, a rayon transport swab containing Stuart's or Amies media may also be used; however, swabs from other suppliers have not been validated.

QUALITY CONTROL

Internal Procedural Controls

The OSOM Ultra Strep A Test provides three levels of procedural controls with each test run:

- The color of the liquid changes from pink to light yellow after Reagent B is added to Reagent A and the extraction reagents are mixed. This is an internal extraction reagent control. The color change means you have mixed the extraction reagents properly. The color change also means that the reagents are functioning properly.
- The red Control Line is an internal positive procedural control. For the Test Stick to be working properly, capillary flow must occur. The Test Stick must absorb the proper amount of sample and the Test Stick must be working properly for the red Control Line to appear.
- A clear background is an internal background negative procedural control. If no interfering substances are in the specimen and the Test Stick is working properly, the background will clear. A discernible result will be seen.

If the red Control Line does not appear the test is invalid. If the background does not clear and interferes with the test result, the test is invalid. Call SEKISUI Diagnostics Technical Service if you experience either of these problems.

External Quality Control Testing

Each kit contains Positive and Negative Control material. The controls are for external quality control testing. Use the Controls to test that the extraction reagents and the Test Sticks are working properly. Also use the Controls to test that you are able to correctly perform the test procedure, including the antigen extraction portion of the test procedure. If you choose, you may use Group A and non Group A Streptococcus ATCC reference strains as external controls. Some commercial controls may contain interfering additives. Therefore SEKISUI Diagnostics recommends that you do not use commercial controls with the OSOM Ultra Strep A Test.

Quality Control requirements should be established in accordance with local, state and federal regulations or accreditation requirements. Minimally, SEKISUI Diagnostics recommends that positive and negative external controls be run with each new lot and with each new untrained operator.

QC Testing Procedure:

Positive Control

- Follow Step 1 in the TEST PROCEDURE section to dispense Reagent A and B into the Test Tube.
- Vigorously mix the Positive Control material. Add 1 free falling drop of the Positive Control from the dropper bottle into the Test Tube.
- Place a clean swab into the Test Tube.
- Follow the Steps 3-5 in the TEST PROCEDURE section to test the swab.

Negative Control

- Follow Step 1 in the TEST PROCEDURE section to dispense Reagent A and B into the Test Tube.
- Vigorously mix the Negative Control material. Add 1 free falling drop of the Negative Control from the dropper bottle into the Test Tube.
- Place a clean swab into the Test Tube.
- Follow the Steps 3-5 in the TEST PROCEDURE section to test the swab.

LIMITATIONS

As with all diagnostic assays, the results obtained by this test yield data that must be used only as an adjunct to other information available to the physician. The following factors must be considered to obtain reliable results:

- The OSOM Ultra Strep A Test is a qualitative test for the detection of Group A Streptococcal antigen. This test detects both viable and non-viable Group A Streptococci, and may yield a positive result in the absence of living organisms.
- The quality of the test depends on the quality of the sample; proper throat swab specimens must be obtained.
  Negative results can occur from inadequate specimen collection or antigen level which is below the detection limit of the test.
- The OSOM Ultra Strep A Test should be used only with throat swab specimens. The use of swab specimens taken from other sites or the use of other samples such as saliva, sputum or urine has not been established.
- This test does not differentiate between carriers and acute infection.
- Pharyngitis may be caused by viral or bacterial pathogens other than Group A Streptococcus.[1,2]
- If the test result is inconsistent with the clinical symptoms, a second throat swab should be collected for repeat testing.

The American Academy of Pediatrics states:[4] "Several rapid diagnostic tests for GAS pharyngitis are available… The specificities of these tests generally are very high, but the reported sensitivities vary considerably. As with throat cultures, the accuracy of these tests is most dependent on the quality of the throat swab specimen, which must contain pharyngeal and tonsillar secretions, and on the experience of the person who is performing the test. Therefore, when a patient suspected of having GAS pharyngitis has a negative rapid streptococcal test, a throat culture should be obtained to ensure that the patient does not have GAS infection." It also states: "Cultures that are negative for GAS infection after 24 hours should be incubated for a second day to optimize isolation of GAS."

EXPECTED RESULTS

Approximately 19% of all upper respiratory tract infections are caused by Group A Streptococci[5]. Streptococcal pharyngitis displays a seasonal variation and is most prevalent during winter and early spring. The highest incidence of this disease is found in crowded populations such as military bases and in school-age children.[6]

PERFORMANCE CHARACTERISTICS

Summary

The study results in this section show that the sensitivities of the OSOM Ultra Strep A Test and the standard single swab culture method are not statistically different. The study also compared the OSOM Ultra Strep A Test to Rigorous Gold Standard and another commercially available rapid test, Inverness Medical—BioStar's Strep A OIA® Max Test***.

Comparison of the Performances of OSOM Ultra Strep A Test, Strep A OIA Max Test and Standard Single Swab Culture Method, by Using Rigorous Gold Standard ("RGS"; Multiple Sample Swab Culture plus Broth Enhanced Pledget Culture) as the Gold Standard

In a hospital clinical lab field evaluation, two swabs (A and B) were collected from each of 302 patients presenting with pharyngitis. Swabs were held in transport tubes with Stuart's modified transport medium until testing. Swabs A and B from each patient were inoculated on separate selective sheep blood agar plates. One swab (Swab A) was then tested by the OSOM Ultra Strep A Test and the other swab (Swab B) was tested by the Strep A OIA Max Test. Plates were incubated for 24–48 hours at 35° C with 5–10% CO_2. All pledgets from the transport tubes were placed aseptically in modified Todd Hewitt Broth (THB) for 16–24 hours at 35°C with 5–10% CO_2. After the initial incubation, the inoculated THB was sub–cultured on SXT agar plates and incubated for 24–48 hours at 35° C with 5–10% CO_2. All presumptive GAS colonies were confirmed with commercially available Strep A test kits. A positive culture from either one of the two swabs or the pledget was considered a Rigorous Gold Standard (RGS) positive.

Of 302 total patients sampled, 94 were found RGS positive and 208 were RGS negative, with a positive rate of 31.1%. The sensitivity of the OSOM Ultra Strep A Test, 92.6% (95% confidence interval (CI): 84.8–96.0%) was the same as the corresponding standard single swab culture, 92.6% (95% CI: 84.8–96.0%). In these studies, the two test methods' sensitivities were not statistically different (p = 0.7811). The sensitivity of the OSOM Ultra Strep A Test was 92.6% and the sensitivity of the Strep A OIA Max Test was 75.5%, with p value of 0.0021. The results are summarized below:

Individual Test Results Compared to the RGS:

Swab A - Culture vs RGS			
	RGS +	RGS -	Total
Culture +	87	0	87
Culture -	7	208	215
Total	94	208	302

Sensitivity: 87/94 = 92.6%
Specificity: N/Aa

Swab A - OSOM Ultra Strep A Test vs. RGS			
	RGS +	RGS -	Total
Ultra +	87	15	102
Ultra -	7	193	200
Total	94	208	302

Sensitivity: 87/94 = 92.6%
Specificity: 193/208 = 92.8%

Swab B - Culture vs RGS			
	RGS +	RGS -	Total
Culture +	82	0	82
Culture -	12	208	220
Total	94	208	302

Sensitivity: 82/94 = 87.2%
Specificity: N/A[a]

Swab B - Strep A OIA Max Test vs RGS			
	RGS +	RGS -	Total
OIA +	71	6	77
OIA -	23	202	225
Total	94	208	302

Sensitivity: 71/94 = 75.5%
Specificity: 202/208 = 97.1%

Summary of the Test Method Sensitivity and Specificity When Compared to the Rigorous Gold Standard:

Test Method	Sensitivity	Specificity
Single Swab Culture A (SSC A)	87/94 (92.6%)	N/A[a]
Single Swab Cuture B (SSC B)	82/94 (87.2%)	N/A[a]
OSOM Ultra Strep A Test (Swab A)	87/94 (92.6%)	193/208 (92.8%)
Strep A OIA Max Test (Swab B)	71/94 (75.5%)	202/208 (97.1%)

Statistical Analysisb for the Sensitivity of the Various Test Methods:

Test Method	Sensitivity	p
SSC A vs. SSC B	87/94 (92.6%) vs. 82/94 (87.2%)	0.3312
OSOM Ultra vs. SSC A	87/94 (92.6%) vs. 87/94 (92.6%)	0.7811
OIA Max vs. SSC B	71/94 (75.5%) vs. 82/94 (87.2%)	0.0581
OSOM Ultra vs. OIA Max	87/94 (92.6%) vs. 71/94 (75.5%)	0.0021

a. N/A, Not applicable, all culture positives are true-positive by definition.

b. A statistical analysis using "The Difference Between Two Independent Proportions" by Fleiss[(7)] was used.

Comparison of the Performances of OSOM Ultra Strep A Test and Standard Single Swab Culture Method, by Using Combined Culture Standard ("CCS"; Single Swab Culture plus Broth Enhanced Pledget Culture) as the Gold Standard

In a field evaluation conducted by a clinical lab for a pediatric group practice, a total of 490 throat swabs were collected from patients presenting with pharyngitis. Swabs were held in transport tubes with modified Stuart's transport media until testing.

Each swab was inoculated on a sheep blood agar plate, then tested by the OSOM Ultra Strep A Test. The plate methods were the same as previously described. All pledgets from the transport tubes were also tested following the enhanced pledget culture method described previously. A positive culture from either the swab or the pledget was considered a Combined Culture Standard (CCS) positive. Of 490 total specimens, 164 were found CCS positive and 326 were CCS negative, with a positive rate of 33.5%. Of the 326 CCS negative specimens, 326 were also negative by the OSOM Ultra Strep A Test, for a specificity of 100% (95% CI: 98.5–100%). Of the 164 CCS positive specimens, 161 and 157 were also positive by the standard single swab culture and the OSOM Ultra Strep A Test, respectively. These equal to sensitivities of 98.2% (95% CI: 94.3–99.2%) and 95.7% (95% CI: 91.1–97.7%) for the standard single swab culture and the OSOM Ultra Strep A Test, respectively. A statistical analysis comparing the sensitivity of the standard single swab culture and the OSOM Ultra Strep A Test, using "The Difference Between Two Independent Proportions" by Fleiss[(7)], showed these two methods were not statistically different (p = 0.3341). The results are summarized below:

Test Results:

Single Swab Culture vs. CCS			
	CCS +	CCS -	Total
Culture +	161	0	161
Culture -	3	326	329
Total	164	326	490

Sensitivity: 161/164 = 98.2%
Specificity: N/A[a]

OSOM Ultra Strep A Test vs. CCS			
	CCS +	CCS -	Total
Ultra +	157	0	157
Ultra -	7	326	333
Total	164	326	490

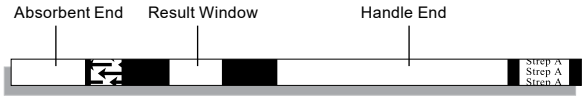
Sensitivity: 157/164 = 95.7%
Specificity: 326/326 = 100%

Statistical Analysis:

Test Method	Sensitivity	Specificity
Single Swab Culture	161/164 (98.2%)	N/A[a]
OSOM Ultra Strep A Test	157/164 (95.7%)	326/326 (100%)
p=	0.3341	N/A[a]

a. N/A, Not applicable, all culture positives are true-positive by definition.

TEST PROCEDURE



STEP 1

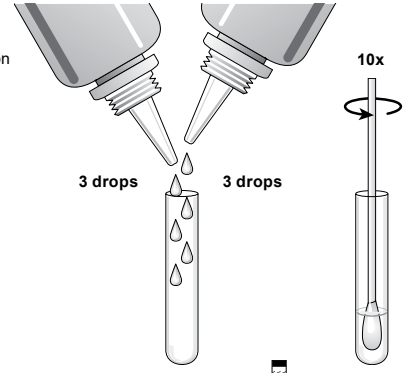
Just before testing, add 3 drops Reagent A (pink) and 3 drops Reagent B to the Test Tube (the solution should turn light yellow).

STEP 2

Immediately put the swab into the Tube.

Vigorously mix the solution by rotating the swab forcefully against the side of the Tube at least ten (10) times. Best results are obtained when the specimen is vigorously extracted in the solution.

Let stand for 2 minutes.



STEP 3

Express as much liquid as possible from the swab by squeezing the sides of the tube as the swab is withdrawn.

Discard the swab.

STEP 4

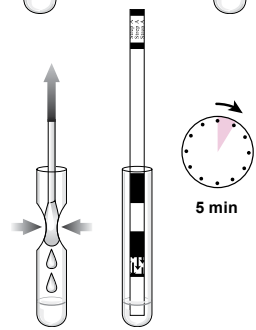
Remove the Test Stick(s) from the container; re-cap the container immediately.

Place the Absorbent End of the Test Stick into the extracted sample.

STEP 5

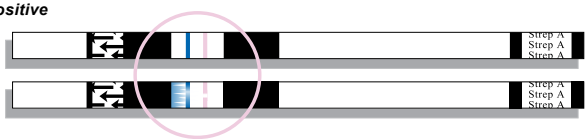
Read results at 5 minutes. Positive results may be read as soon as the red Control Line appears. Negative results must be confirmed at 5 minutes.

Results are invalid after the read time.
The use of a timer is recommended.



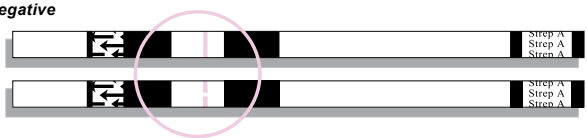
INTERPRETATION OF TEST RESULTS

Positive



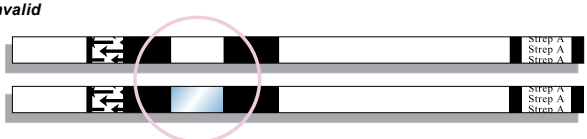
A blue Test Line and a red Control Line is a positive result. A positive result means that the assay detected Group A Streptococcus antigen in the specimen. Note that the blue line can be any shade of blue and can be lighter or darker than the line in the picture.

Negative



A red Control Line but no blue Test Line is a negative result. A negative result means that no Group A Streptococcus antigen was detected, or the levels of antigen in the specimen were below the detection level of the assay.

Invalid



If after 5 minutes, no red Control Line appears or background color makes reading the red Control Line impossible, the result is invalid. If this occurs, repeat the test using a new sample or contact SEKISUI Diagnostics Technical Service.

Notes

A blue or red line that appears uneven in color density is still considered a valid line. In some cases, a trail of color may remain in the background; as long as the Test Line and Control Line are visible, the results are valid.

Evaluation of the Performance of OSOM Ultra Strep A Test by Using Standard Single Swab Culture Method as the Gold Standard

In a two site field evaluation, throat swabs were collected from patients presenting with pharyngitis. Each swab was inoculated on a sheep blood agar plate, then tested by the OSOM Ultra Strep A Test. Plates were incubated for 24–48 hours at 35° C with 5–10% CO_2. Presumptive GAS colonies were confirmed with commercially available Strep A test kits. When the standard single swab culture method was used as the gold standard, the combined results from these two sites showed that the OSOM Ultra Strep A Test had a sensitivity of 96.4% (239/248; 95% CI: 93.0–97.9%), a specificity of 96.3% (524/544; 95% CI: 94.3–97.5%), and an overall agreement of 96.3%. The results are summarized below:

Culture Density	OSOM Ultra Strep A Results
4+ (predominant growth)	89/89 (100%)
3+ (>50 colonies)	90/91 (98.9%)
2+ (11–50 colonies)	45/46 (97.8%)
1+ (<10 colonies)	15/22 (68.2%)
Total Positive (Sensitivity)	239/248 (96.4%)
Negative (Specificity)	524/544 (96.3%)

CROSS-REACTIVITY

The following organisms tested at levels of approximately 1 x $10^{(8)}$ organisms/test were all found to be negative when tested with the OSOM Ultra Strep A Test.

Streptococcus Group B	Enterococcus faecalis	Pseudomonas aeruginosa
Streptococcus Group C	Escherichia coli	Bordetella pertussis
Streptococcus Group D	Staphylococcus aureus	Neisseria meningitidis
Streptococcus Group F	Staphylococcus epidermidis	Neisseria gonorrhoeae
Streptococcus Group G	Corynebacterium diptheria	Neisseria sicca
Streptococcus pneumoniae	Serratia marcescens	Neisseria subflava
Streptococcus sanguis	Candida albicans	Branhamella catarrhalis
Streptococcus mutans	Klebsiella pneumoniae	Hemophilus influenza

POL STUDIES

An evaluation of the OSOM Ultra Strep A Test was conducted at three physicians offices where testing was performed by personnel with diverse educational backgrounds. Each site tested the randomly coded panel consisting of negative (6), low positive (3) and moderate positive (3) specimens for three days. The results obtained had 100% agreement (108/108) with the expected results.

REFERENCES

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6. Wannamaker, L.W., Differences Between Streptococcal Infections of the Throat and of the Skin, N. Eng. J. Med., 282: 23–31, 78–85, 1970.
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ASSISTANCE

For assistance, call SEKISUI Diagnostics Technical Service at 800-332-1042.

RE-ORDER

No. 149 (50 Tests)

SYMBOLS

LOT	Batch code
REF	Catalog number
Rx ONLY	Caution: Federal Law restricts this device to sale by or on the order of a licensed practitioner.
	Consult instructions for use
Σ n	Contains sufficient for <n> tests
	Exclamation Mark
IVD	*In Vitro* Diagnostic Medical Device
	Manufacturer
	Temperature limit
	Recycle
	Use by date

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