The chlamydiae are a large group of obligate intracellular parasites closely related to gram-negative bacteria. There are two species: Chlamydia trachomatis, primarily a human pathogen; and Chlamydia psittaci, primarily an animal pathogen (1,2).

The chlamydial infections of man – trachoma, inclusion conjunctivitis, and lymphogranuloma venereum – have been recognized and studied for many years. However, the chlamydiae have only recently been identified as important etiological agents in sexually transmissible diseases. The prevalence of these chlamydia-related diseases and the population at risk are thought to exceed those of gonorrhea (3). Chlamydia trachomatis is now known to cause urogenital (4), epidemic keratoconjunctivitis (5), cervicitis, pelvic inflammatory disease (6), infant pneumonia (7-10), and infant conjunctivitis (11). It has also been implicated in Reiter’s syndrome and premature birth. In both sexes, the infection may be asymptomatic (1,12-21).

The chlamydiae cannot synthesize ATP and therefore they depend on the host cell for energy. The replicative cycle of the chlamydiae lasts approximately 48-72 hours and begins with the attachment of an infectious particle – an elementary body – to the surface of the susceptible cell. The elementary body enters the cell in a phagocytic vesicle derived from the host cell’s surface membrane and then reorganizes to form a reticulate (or initial) body – the metabolically active, replicating reticulate body. The antibodies to form a reticulate (or initial) body. When specimen is applied directly to a slide well glass slide, diagnosis should be based only on the presence of elementary bodies. Most staining methods cannot detect elementary bodies; thus, diagnosis of chlamydial infection has been based on cell culture, technically demanding and time consuming procedure. Since the MicroTrak® Chlamydia trachomatis Direct Specimen Test can detect and resolve elementary bodies in direct patient specimens, this test provides a simple, rapid procedure for the diagnosis of chlamydial infection (32-35).

Monoclonal antibodies have been prepared against the major outer membrane protein present in all 15 known human serovars of C. trachomatis and in both forms of the organism: the infectious elementary body, and the metabolically active, replicating reticulate body. The antibodies are labeled with fluoresce isothiocyanate (36,37). When specimen is applied directly to a slide well and stained, the antibody conjugate binds specifically to any C. trachomatis present in the smear. A rinse step removes unbound antibody. When slides are viewed under a fluorescence microscope, stained smears from Chlamydia-positive specimens contain apple-green elementary or reticulate bodies contrasted by the reddish-brown background of the counterstained cells (32-35).

In cell culture C. trachomatis is detected by the presence of inclusion bodies, whereas a specimen swabbed directly from a C. trachomatis-infected cervix, urethra, rectum, or nasopharynx typically displays extracellular elementary bodies as its pathognomonic feature (21). While a direct conjunctival specimen may display extracellular elementary bodies or inclusion bodies or both (32), diagnosis should be based only on the presence of elementary bodies. Most staining methods cannot detect elementary bodies; thus, diagnosis of chlamydial infection has been based on cell culture, technically demanding and time consuming procedure. Since the MicroTrak® Chlamydia trachomatis Direct Specimen Test can detect and resolve elementary bodies in direct patient specimens, this test provides a simple, rapid procedure for the diagnosis of chlamydial infection (32-35).

<table>
<thead>
<tr>
<th>Catalog Number</th>
<th>Product Description</th>
<th>Quantity/Volume</th>
</tr>
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<tbody>
<tr>
<td>8H149UL</td>
<td>MicroTrak® Chlamydia trachomatis Direct Specimen Test, consisting of: Chlamydia trachomatis Reagent*</td>
<td>60 tests</td>
</tr>
<tr>
<td></td>
<td>Reconstitution Diluent</td>
<td>2.0 ml</td>
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<tr>
<td></td>
<td>Mounting Fluid</td>
<td>5.0 ml</td>
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<td>6.0 ml</td>
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<tr>
<td>8H159UL-S</td>
<td>MicroTrak® Chlamydia trachomatis Collection Kit**, each kit consisting of: Single-well glass slide</td>
<td>20 kits</td>
</tr>
<tr>
<td></td>
<td>Dacon swabs (one large, one small)</td>
<td>1 slide</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2 swabs</td>
</tr>
</tbody>
</table>

** The direct specimen reagent is supplied lyophilized. The indicated volume is that required for reconstitution.

** Sold separately.

Reagent and Reconstitution Diluent

The reagent contains fluorescein-labeled, purified murine monoclonal antibodies specific to C. trachomatis. Evans Blue counterstain, and suppressors of nonspecific staining in a protein-stabilized buffer solution. The reconstitution diluent contains 0.1% sodium azide in deionized water.

Precaution: The MicroTrak® Chlamydia trachomatis Direct Specimen Test is designed for in vitro diagnostic use.

Precaution: The direct specimen reagent and reconstitution diluent contain sodium azide. Sodium azide may react with lead and copper plating to form highly explosive metal azides. On disposal, flush with a large volume of water to prevent azide buildup.

The following instruction should be adhered to when opening the silver flip-seal cap as it has a sharp edge after opening:

- A tweezers, needle-nose pliers, forceps, de-cappers, spatula or similar type of object should be used to open and peel off the flip-seal from the vial. When doing this action, ensure it is done outwards, away from the body.
- Latex gloves should also be worn to provide further protection to the user.

To reconstitute the lyophilized reagent, remove the metal seal and rubber stopper from the reagent vial (10). Invert the reconstituted reagent 5-10 times (10). Place the reagent stopper and gently swirl the reagent to dissolve the powder. Record the reconstitution date on the reagent vial label. After reconstitution, the reagent must be kept at a room temperature of 20-25°C for 30 minutes before use.

Store the reagent at 2-8°C when not in use. Do not freeze or expose to temperatures above 32°C. Do not expose to strong light. When handled as directed, the reconstituted reagent can be used for 12 weeks.

Mounting Fluid

Mounting fluid at pH 9.4 contains phosphate buffer, glycerol, and an agent to retard photobleaching. Store the mounting fluid at 2-8°C.

Control Slides

C. trachomatis Positive Control slides contain fixed mammalian cells and elementary and reticulate bodies that approximate the appearance of chlamydial organisms on a positive sample. Diagnosis of patient specimen should be based on the presence of elementary bodies only. Negative control slides contain mammalian cells only. Slides are provided in individual, sealed foil pouches containing desiccant. Store the sealed slides at 2-8°C. Before removing a slide from its foil pouch, leave it at room temperature of 20-25°C for at least five minutes. Use the slide immediately after removing it from the pouch. When handled as directed above, unstained control slides can be used until the expiration date printed on the foil pouch.

Precaution: The chlamydial antibodies on MicroTrak® positive control slides have been shown to be noninfectious in culture; however, users are advised to observe the same safety precautions as employed when handling and disposing of other potentially infectious biological material.

Note: Do not use the reagent, reconstitution diluent, control slides, or mounting fluid after the expiration dates printed on the container labels.

5. SPECIMEN COLLECTION

Specimen collection is a critical step in any diagnostic procedure based on the microscopic examination of specimen taken directly from patients. Several references on specimen collection procedures are available (13,38-40); abbreviated procedures are presented here.

Precaution: During the collection and processing of samples, users are advised to observe the same safety precautions as employed when handling and disposing of other potentially infectious materials (13).

Urethral Samples (Males)

- Patient preferably should not have urinated one hour prior to sampling.
  1. Insert small Dacon swab 2-4 cm into urethra.
  2. Rotate swab and withdraw.

Cervical Samples (Swab)

- The large or small swab should be used to sample pregnant patients or patients with a small cervical os.
  1. Wipe exocervix with cotton or Dacon swab to remove excess mucus. Dispose of swab.
  2. Insert small or large Dacon swab into endocervical canal until most of Dacon tip is not visible.
  3. Rotate swab for 5-10 seconds inside endocervical canal.
4. Withdraw swab without touching any vaginal surfaces.

Rectal Samples
- Samples should be collected only from symptomatic patients.
- Only technicians proficient in the interpretation of urogenital specimens should examine rectal specimens; check with the laboratory for availability of qualified technicians before submitting rectal specimens.

1. Insert large Dacron swab approximately 3 cm into anal canal.
2. Move swab from side to side to sample crypts.
3. Withdraw swab. If fecal contamination occurs, discard swab and obtain another specimen.

 Conjunctival Samples
- Samples should be collected only from symptomatic patients.

1. Apply a topical proparacaine-anesthetic to the eye or eyes (optional).
2. Using the small swab, thoroughly swab the inner surface of the lower, then the upper eyelid. If samples are taken from both eyes, use the swab on the less affected eye first to avoid further contamination of that eye.

In conjunctival specimens, at least 10 intact columnar epithelial cells should appear on the slide to ensure specimen adequacy.

 Nasopharyngeal Samples
- Samples should be collected only from symptomatic patients.

Collect specimens from the posterior nasopharynx by nasal swab or nasal aspirate using a standard collection method.

Slide Preparation (Swab)
- Slides made from swab specimens should be prepared immediately after specimen collection.

1. Firmly roll one side of swab over top half of well, then roll other side over bottom half. Cover entire well evenly and stay within well perimeter.
2. Check coverage.
3. Allow specimen to completely air dry.
4. Lay slide flat; flood with 0.5 ml methanol fixative and let entire quantity evaporate. To speed evaporation, tip slide after 5 minutes to drain excess fixative.
5. For best results, store/transport either at a room temperature range of 20-30°C or refrigerated at 2-8°C, and stain within 7 days of collection. If not stained within 7 days, fixed specimen should be stored at -20°C.

Slide Preparation (Nasal Aspirate)
1. Vortex specimen gently to break up mucus.
2. Place one drop of the vortexed specimen on well. Cover entire well and stay within well perimeter.
3. Check coverage.
4. Allow specimen to completely air dry.
5. Lay slide flat; flood with 0.5 ml methanol fixative and let entire quantity evaporate. To speed evaporation, tip slide after 5 minutes to drain excess fixative.
6. For best results, store/transport either at a room temperature range of 20-30°C or refrigerated at 2-8°C, and stain within 7 days of collection. If not stained within 7 days, fixed specimen should be stored at -20°C.

Note: To facilitate specimen collection, use the MicroTrak® Chlamydia trachomatis Specimen Collection Kit. Also, see Section 12, Critical Parameters, and Section 12, Problem-Solving.

6. PROCEDURE

Materials Provided
MicroTrak® Chlamydia trachomatis Direct Specimen Test (contains reagent, reconstitution diluent, and mounting fluid)

Materials Required But Not Provided
MicroTrak® Chlamydia trachomatis Direct Specimen Test Control Slide Pack (contains C. trachomatis Positive Control Slides and Negative Control Slides)
Recommended: MicroTrak® Chlamydia trachomatis Specimen Collection Kit (contains methanol in glass ampule with disposable dispenser; single-well slide that allows specimen and reagent concentration for optimal sensitivity; large and small swabs; and a transport container with instructions for collection)

If the MicroTrak® Chlamydia trachomatis Specimen Collection Kit is not used, care should be taken to obtain specimen collection materials with the specifications described below:
- Microscope slides with 8 mm wells – methanol resistant paint required
- Dacron swab
- Methanol fixative
- Container for slide transport to lab

Cotton or Dacron swab to clean exocervix
-Micropipette – 30 pl
-Blotting paper
-Moist chamber
-Rinse – deionized or distilled water
-Coverslips – 22 x 40-60 mm, #1 recommended

Immersion of suitable for fluorescence
Fluorescence microscope with filter system for fluorescent isocyanate (FITC), i.e., maximum excitation wavelength = 490 nm, mean emission wavelength = 520 nm; 400-500x and 630-1000x magnification

Note: A well-functioning fluorescence microscope is crucial. Variations in bulb wattage, intensity and alignment, type of illumination, and filters may affect test performance. Use a positive control to verify adequate functioning of the staining procedure and microscope.

Instructions
- Use of asceptic technique throughout this procedure is recommended.

A. Setup
1. Prepare the reagent according to the directions in Section 4.
2. Allow the reagent, control slides, and patient specimens to reach room temperature before use. To prevent condensation, leave the control slides in their foil pouches with desiccant while bringing them to room temperature.
3. Swill the reagent vial to mix liquid thoroughly before use.

Note: To verify the performance of the staining procedure and the microscope, stain and read both a C. trachomatis positive control slide and a negative control slide in parallel with each series of patient specimens. Treat controls exactly as specimens throughout the procedure. Use the appearance of elementary bodies on a positive C. trachomatis control slide as a reference in evaluating elementary bodies on patient specimens.

Precaution: The chlamydiae on MicroTrak® positive control slides have been shown to be noninfectious in culture; however, users are advised to observe the same safety precautions as employed when handling and disposing of other potentially infectious biological material.

B. Staining and Mounting
1. Add 30 pl of reagent to each control slide and fixed specimen, making sure the entire area of the well is covered. Return the reagent to refrigeration immediately after staining. (Also see Section 12, Critical Parameters.)

Precaution: Observe the same safety precautions as employed when handling and disposing of other potentially infectious biological material.

Note: If necessary, spread the reagent over the smear with the pipette tip, taking care not to disturb the fixed specimen. After spreading, always change pipette tips.

2. Incubate the slides for 15 minutes at room temperature in a well-humidified chamber. Do not allow the antibodies to dry on the specimen; drying will cause nonspecific binding. To prevent drying, periodically inspect the chamber for adequate humidification and remove from incubation promptly at 15 minutes. (Also see Section 13, Problem-Solving.)
3. Aspirate the excess reagent.
4. Rinse the slides by gently agitating them in deionized or distilled water for 10 seconds. Gently shake off excess water and wick the remaining moisture from the edge of each slide with blotting paper. Allow them to air dry.
5. Add a drop of mounting fluid to the center of each slide well. Place a coverslip on top of the drop and remove all air bubbles.

C. Reading

Read the slides using a suitable fluorescence microscope (see Materials Required But Not Provided). For optimum clarity, use oil objectives: a 40x or 50x oil objective for screening and a 63x or 100x oil objective for high magnification. (Also see Section 12, Critical Parameters.)

Note: If it is not possible to read the slides immediately after staining, store them in the dark at 2-8°C and read them within 24 hours for best results. Allow the slides to reach room temperature before reading or condensation will occur, obscuring the specimens.

7. EVALUATION OF TEST RESULTS

Scan the entire 8 mm well carefully for chlamydial organisms.

Chlamydial organisms – The most common forms in C. trachomatis-positive direct specimens are extracellular elementary bodies (32), which appear as individual pin-points of medium to bright apple-green fluorescence. At higher magnification, elementary bodies (approximately one one-hundredth the size of an intact cell) appear evenly fluorescing, smooth-edged, and disc-shaped. Diagnosis should be based on the presence of elementary bodies only. The positive control slide should be used to aid in diagnosis.

Other forms of the organism may also be present. Some chlamydiae (approximately 2-3 times the size of an elementary body) may stain with a peripheral halo. These represent immature organisms, reticulate bodies, or forms intermediate between elementary and reticulate bodies released from ruptured inclusions. Intracellular chlamydial inclusions are rarely seen.

Other fluorescing material – Any fluorescing particles which are irregularly shaped, differ in size or appearance from the chlamydial elementary bodies described above, or fluoresce yellow, white, or red rather than apple-green should be considered artifact. Additionally, any particles emitting an intensely bright, “glassy” fluorescence or a duller olive-green color should be disregarded.
The monoclonal antibodies used in the MicroTrak® Chlamydia trachomatis Direct Specimen Test reagent are highly specific for the major outer membrane protein of C. trachomatis. However, certain strains of bacteria that can bind some immuno globulins to their surfaces may bind MicroTrak® antibody (an immunoglobulin) and appear fluorescent (41-43). This phenomenon, when it occurs, has been observed mainly in rectal specimens. In all cases of bacterial staining, C. trachomatis elementary bodies can be distinguished from bacteria by characteristic morphology. Chlamydial elementary bodies are approximately 300 nm in diameter and stain evenly throughout the entire surface. Bacterial elementary cells are generally 2-3 times larger than elementary bodies and tend to stain at the rim, producing a doughnut appearance. Always use the positive control slide as a guide to the size, shape, and staining pattern of elementary bodies. Chlamydial reticulate bodies, which also appear on the positive control slide, resemble bacteria and cannot be used as a guide to the interpretation of patient samples.

Control slides—At least 10 elementary bodies with a contrasting reddish-brown background of contaminants should be identifiable on the positive control slide. The negative control slide should not display fluorescence although the counterstained cells should be visible. The appearance of the elementary bodies on the positive control slide should be used as a reference in evaluating elementary bodies on patient specimens. If the positive and negative controls cannot be distinguished from one another, the test is invalid. See Section 13, Problem-Solving, for possible causes of discrepant control results.

Negative results—Reported when fixed, stained smears are free of chlamydial organisms. Test result reports should indicate whether or not columnar or cuboidal epithelial cells were present. The sensitivity of any test for C. trachomatis depends on the presence of columnar or cuboidal epithelial cells. In clinical trials, investigators agreed that 10-20 columnar or cuboidal epithelial cells were sufficient for accurate diagnosis of Chlamydia trachomatis.

Positive diagnosis—Trinity Biotech plc. suggests that laboratories use the criteria described below for positive diagnoses when first using the test. With experience, laboratories may establish lower cut-offs of chlamydia elementary bodies based on individual proficiency data.

Sensitivity and specificity data generated in clinical trials were based on these criteria:

- The presence of 10 or more chlamydia elementary bodies in urgenital, conjunctival, and nasopharyngeal aspirate specimens.
- The presence of four or more chlamydia elementary bodies in nasopharyngeal swab specimens. This cut-off is recommended because in clinical trial studies, few elementary bodies were seen in nasopharyngeal swab specimens than in aspirate specimens.
- The presence of two or more chlamydia elementary bodies in rectal specimens. This cut-off is recommended because (1) rectal specimens are obtained from an anatomic site with a much greater surface area than the urethra or endocervical canal, (2) rectal specimens typically are collected blindly without reference to localized areas of inflammation, and (3) levels of infection in the rectum appear to be lower than in the urogenital tract.

Note: If fewer chlamydia elementary bodies than the laboratory’s established criteria are seen, infection should be suspected; to establish the diagnosis, another sample should be taken and tested.

### 8. INTERPRETATION OF TEST RESULTS

In populations with a high prevalence of chlamydial infections, a positive MicroTrak® Chlamydia trachomatis Direct Specimen Test result is considered positive for Chlamydia trachomatis infection. In populations with low disease prevalence (5% or less), a positive MicroTrak® Chlamydia trachomatis Direct Specimen Test result should be interpreted cautiously. See the example in Section 10, Expected Values.

### 9. LIMITATIONS

1. Performance of the MicroTrak® Chlamydia trachomatis Direct Specimen Test has been established only for the detection and identification of C. trachomatis in urgenital, rectal, conjunctival, and nasopharyngeal specimens. Rectal, conjunctival, and nasopharyngeal specimens should be collected only from symptomatic patients.

2. In populations with low disease prevalence (5% or less), a positive MicroTrak® Chlamydia trachomatis Direct Specimen Test result should be interpreted cautiously.

3. No data were available on the performance of the MicroTrak® Chlamydia trachomatis Direct Specimen Test in the determination of the patient’s response to therapy. Use of the test in such situations should be evaluated along with culture tests.

4. Optimal performance of this test is dependent on the collection of a good patient specimen and proper slide smearing technique.

5. The monoclonal antibodies used in the MicroTrak® Chlamydia trachomatis Direct Specimen Test reagent are highly specific for the major outer membrane protein of C. trachomatis. However, certain strains of bacteria that can bind some immunoglobulins to their surfaces may bind MicroTrak® antibody (an immunoglobulin) and appear fluorescent (41-43). In all cases of bacterial staining, C. trachomatis elementary bodies can be distinguished from bacteria by characteristic morphology. Always use the positive control slide as a guide to the size, shape, and staining pattern of elementary bodies. Chlamydial reticulate bodies, which also appear on the positive control slide, resemble bacteria and cannot be used as a guide to the interpretation of patient samples. (See Section 7, Evaluation of Test Results.)

6. While the MicroTrak® Chlamydia trachomatis Direct Specimen Test can be used to test specimens for inclusion conjunctivitis, it has not been validated for testing specimens for trachoma.

### 10. EXPECTED VALUES

#### Urogenital and Rectal Specimens

The MicroTrak® Chlamydia trachomatis Direct Specimen Test was studied on samples from 2728 (1517 female, 1211 male) patients in populations with varying prevalences (7-23%) of chlamydial infection as determined by conventional cell culture methods. (See Section 11, Performance.)

For urogenital specimens, the sensitivity of the MicroTrak® Chlamydia trachomatis Direct Specimen Test was 92% compared to culture using the MicroTrak® Chlamydia trachomatis Culture Confirmation Test. The specificity of the MicroTrak® Direct Test was 98% compared to the MicroTrak® Culture Confirmation Test.

For rectal specimens, the sensitivity of the MicroTrak® Chlamydia trachomatis Direct Specimen Test was 95% compared to culture using the MicroTrak® Chlamydia trachomatis Culture Confirmation Test. The specificity of the MicroTrak® Direct Test was 100% compared to the MicroTrak® Culture Confirmation Test.

#### Conjunctival Specimens

The MicroTrak® Chlamydia trachomatis Direct Specimen Test was studied on samples from 98 neonates in a population with a high prevalence of chlamydial infection as determined by a conventional cell culture method. (See Section 11, Performance.) The sensitivity of the MicroTrak® Chlamydia trachomatis Direct Specimen Test was 99% compared to culture using the MicroTrak® Chlamydia trachomatis Culture Confirmation Test. The specificity of the MicroTrak® Direct Test was 99% compared to the MicroTrak® Culture Confirmation Test.

#### Nasopharyngeal Specimens

The MicroTrak® Chlamydia trachomatis Direct Specimen Test was studied on samples from 302 infants diagnosed as having atelectic pneumonia or lower respiratory tract infections. The sensitivity of the MicroTrak® Chlamydia trachomatis Direct Specimen Test was 92% compared to culture using the MicroTrak® Chlamydia trachomatis Culture Confirmation Test. The specificity of the MicroTrak® Direct Test was 99% compared to the MicroTrak® Culture Confirmation Test.

#### Prevalence

Theoretically, in a population with a low prevalence of Chlamydia trachomatis infection, there is a corresponding increased demand for test specificity.

Although the specificity of the MicroTrak® Chlamydia trachomatis Direct Specimen Test with respect to one cell culture method is 98% (see Table 1), a significant number of positive MicroTrak® Chlamydia trachomatis Direct Specimen Test results may not agree with cell culture results. In populations of low prevalence (5% or less) of chlamydial infection, for example, in a theoretical test population with a 5% prevalence of venereal chlamydial infection, and given a test sensitivity of 92% and a specificity of 98%, a positive MicroTrak® Chlamydia trachomatis Direct Specimen Test result would be expected to agree with the culture result in approximately 71% of the cases. A negative MicroTrak® Chlamydia trachomatis Direct Specimen Test result would be expected to agree with the culture result in greater than 99% of the cases. Some proportion of the discordant results may represent false negative cultures, although that proportion has not been conclusively established.

### 11. PERFORMANCE

Eight independent laboratories compared the MicroTrak® Chlamydia trachomatis Direct Specimen Test with reference tissue culture techniques. A total of 1104 urethral specimens from males, 1361 cervical specimens, 263 rectal specimens, 98 neonatal conjunctival specimens, and 302 nasopharyngeal specimens were collected with swabs and smeared onto slides. Each swab was then used to inoculate a culture cell.

For purposes of evaluating test results in the comparison, cell culture was assumed to be 100% sensitive and specific.

Table 1 shows the results of testing urogenital specimens by both the MicroTrak® Chlamydia trachomatis Direct Specimen Test and the MicroTrak® Chlamydia trachomatis Culture Confirmation Test (primary cultures).

Table 2 shows the results of testing urogenital specimens by both the MicroTrak® Chlamydia trachomatis Direct Specimen Test and loddine staining (passaged cultures).

Table 3 shows the results of testing rectal specimens by both the MicroTrak® Chlamydia trachomatis Direct Specimen Test and the MicroTrak® Chlamydia trachomatis Culture Confirmation Test (primary cultures).
Table 4 shows the results of testing neonatal conjunctival specimens by both the MicroTrak® Chlamydia trachomatis Direct Specimen Test and the MicroTrak® Chlamydia trachomatis Culture Confirmation Test.

<table>
<thead>
<tr>
<th>MicroTrak® Direct</th>
<th>MicroTrak® Culture</th>
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<tbody>
<tr>
<td>Study 1</td>
<td>Study 2</td>
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S36: Wear suitable protective clothing.

Prepared in accordance with requirements for EEC label.

EINECS 231-448-7
EINECS 231-511-8
EINECS 247-582-1
EINECS 200-295-5

Notice: Adulteration of reagents, use of instruments without appropriate capabilities, or other failure to follow instructions as set forth in this labeling can affect performance characteristics and stated or implied label claims.

Referenced Sources:


GUIDE TO SYMBOLS

- Consult Instructions for Use
- Store at 2-8°C
- For in vitro Diagnostic Use
- Batch code
- Use by
- Mounting medium
- Negative Control
- Reconstitution diluents
- Reagents
- Harmful
- Highly flammable