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| Shigella Antisera Typing QC |
| **Purpose** | This procedure provides instructions for performing SHIGELLA ANTISERA TYPING QC. |
| **Policy Statements** | This procedure applies to laboratory personnel who perform plate reading. |
| **Materials** |  |  |  |  |
|  | **Reagents** | **Supplies** | **Equipment** |
|  | * Shigella Group A grouping antisera − Cardinal Health product number 4341025
* Shigella Group B grouping antisera, − Cardinal Health product number 4341027
* Shigella Group C grouping antisera − Cardinal Health product number 4341028
* Shigella Group D grouping antisera − Cardinal Health product number 4341031
* Antisera are stable until product expiration date on label when stored at 2-8°C.
* Do not expose reagents to room temperature for long periods of time.
* Discard any antiserum which becomes cloudy during storage.
* Do not subject antisera to repeated freezing and thawing. Such treatment is detrimental to the antibody content.
 | * Sterile 0.85% Saline
* Wooden applicator sticks
* Disposable Petri dish
* China Marker
* Falcon tubes
 | • Orbital mixing device (optional) |
| **Sample** | * Positive control: Well isolated 18-24 hour old colonies of corresponding Shigella group organism as listed on MC 8.6f Shigella Typing Quality Control form.
* Negative control: Well isolated 18-24 hour old colonies of an secondary Shigella species organism

Strains for use as QC:G45 Group A - Shigella dysenteriae ATCC13313G43 Group B - Shigella flexneriG44 Group C - Shigella boydiiG22 Group D - Shigella sonnei ATCC25931  |
| **Special Safety Precautions** | Microbiologists/virologists are subject to occupational risks associated with specimen handling. Refer to the safety policies located in the safety section of the *Microbiology Procedure Manual*and the *Virology Procedure Manual***:**1. *Biohazard Containment*
2. *Safety in the Microbiology/Virology Laboratory*
* *Biohazardous Spills*

Shigella dysenteriae and Shigella species in general are highly infectious organisms. Use appropriate PPE while handling organisms and performing QC. |
| **Quality Control** | * Perform quality control with each new lot or shipment prior to use.
* Perform quality control semiannually following DESK3 Maintenance Schedule.
* Refer to MC 8.6f Shigella Typing Quality Control.
* If there is a QC failure, document observation, notify Microbiology Supervisor and call BD technical service at 1-800-638-8663.
* Do not report patient results until the problem has been resolved.
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| **Procedure** |  |
|  | 1. Make a heavy (milky) suspension of the known Shigella sp. isolate in 0.85% saline solution labeled with the appropriate Shigella group.

(Alternatively, a drop of saline and a small portion of a well-isolated colony may be used.)1. Place a drop of the antisera to be tested into 2 wells of a Petri dish.
2. Add one drop of the positive control group to one of the ringed wells, and one drop of the negative control to the other well containing Shigella sp. antiserum.
3. Mix thoroughly with an applicator stick to achieve a homogenous mixture.
4. Gently rock the Petri dish for one minute or use the mechanical rotator.
5. Examine for agglutination, over the MicroScan light box.
6. Record results on form MC 8.6f Shigella Typing Quality Control, including the Shigella species used as a negative control.
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| **Interpretation/ Results** | 1. Read the results as follows:

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| 4+ | 100% agglutination; background is clear to slightly hazy |
| 3+ | 75% agglutination; background is slightly cloudy |
| 2+ | 50% agglutination; background is moderately cloudy |
| 1+ | 25% agglutination; background is cloudy |
| -- | No agglutination  |

1. Positive result: 3+ or greater agglutination is a positive result.
2. Negative result: Should show no agglutination. If agglutination occurs, the culture is rough and cannot be tested. Subculture to a non-inhibitory medium, incubate and test the organism again.
3. A partial (less than 3+) or delayed agglutination reaction should be considered negative.
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| **Method Performance Specifications** | * All materials and equipment must be at room temperature at the time of test performance.
* Adhere strictly to the time limitations on the tests.
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| **Result Reporting** | Record results on form MC 8.6f Shigella Typing Quality Control |
| **References** | * Difco Laboratories (1998). The Difco manual, 11th ed. Sparks, MD: Becton, Dickinson and Company
* Becton, Dickinson and Company. (9/2014). Shigella antisera for the serological identification of Shigella: Product insert. Sparks, MD: Becton, Dickinson and Company
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| **Training Plan/ Competency Assessment** | **Training Plan** | **Initial Competency Assessment** |
| 1. Employee must read the procedure
2. Employee will observe trainer performing the procedure.
3. Employee will demonstrate the ability to perform procedure, record results and document corrective action after instruction by the trainer.
 | 1. Direct observation. |
| **Historical Record** |  |  |  |  |
|  | **Version** | **Written/Revised by:** | **Effective Date:** | **Summary of Revisions** |
| 1 | David Helfinstine / Sue DeMeyere | 11/10/2017 | Initial Version, antigen discontinued by manufacturer, using organism instead. |
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| **Archived by:** |  | **Archived Date:** |  |