Enteric Bacterial PCR BD MAX Kit

Frequency of QC Testing
Each new lot or shipment and every 30 d while in use.

Control Organisms
- Positive External Control: Pooled, diluted suspensions of *Campylobacter jejuni* ATCC 33291, *E. coli* O157:H7 ATCC 35150, *Salmonella enteritidis* ATCC 14028, and *Shigella sonnei* ATCC 9290.
- Negative External Control: Saline.

Procedure and Expected Results
External Controls
1. Suspensions of the control strains should be prepared in saline to a turbidity of 0.5 McFarland (~1.0 X 10^8 CFU/mL) from isolated colonies. Dilute the *Salmonella, Shigella,* and *E. coli* organisms 1:10 and the *Campylobacter* 1:100. Dilute each suspension 2:5. Combine equal portions of each control suspension to obtain a final concentration of ~1.0 X 10^6 CFU/mL (for *Salmonella, Shigella*, and *E. coli*) and ~1.0 X 10^5 CFU/mL (for *Campylobacter*).
2. Suspensions may be frozen in aliquots at -70 °C and thawed prior to use.
3. Dip a separate 10-µL loop into each bacterial suspension and inoculate the sample buffer tubes.
4. Follow testing protocol outlined in the BD MAX™ Bacterial Enteric Panel Procedure.
5. All quality control results should be entered into the LIS. Notify supervisor if results are not as expected.

Computer Entry of Results
Function: MQCE
Select: TESTQC
Category: UNSCHEDULED
Item Code: MAXBEN
Results for kit QC: NEG, POS

Entering New Lots
MFG Code: BD
Item: MAXBEN

Department of Microbiology
QC Procedures

Rapid ESBL for Blood Cultures

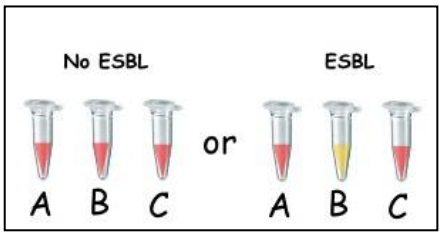
Frequency of QC testing
Each day of patient testing.

Control organisms
Control material consists of blood cultures spiked with 0.1 mL of a 0.5 McFarland suspension of each control strain and incubated overnight. New control cultures should be inoculated on Monday of each week.

- *E. coli* ATCC 25922 (ESBL-negative)
- *E. coli* (ESBL-positive) clinical isolate previously characterized by CLSI ESBL disk confirmation test. Do not use *K. pneumoniae* ATCC 700603. This strain contains an uncommon ESBL phenotype that reacts weakly with the rapid ESBL assay.

Procedure
1. Retrieve a set of Reagent A, B, and C from the -70°C freezer for each control and patient sample.
2. Under a biosafety hood, transfer 1.5 mL of a positive blood culture to a 2-mL screw-cap microcentrifuge tube using a 3-cc syringe with a 20-gauge blunt transfer needle.
3. Add 150 µL of Triton X-100 Surfact-Amps® Detergent.
4. Cap the tube, and vortex for 30 s.
5. Let tube sit for 5 min.
6. Centrifuge at 13,000 x *g* for 2 min.
7. Under a biosafety hood, use a fine-tip transfer pipette to remove and discard the supernatant in the biohazardous waste.
8. Suspend the pellet in 1,000 µL of distilled water by mixing up and down with the pipette.
9. Centrifuge at 13,000 x *g* for 2 min.
10. Under a biosafety hood, use a fine-tip transfer pipette to remove and discard the supernatant in the biohazardous waste.
11. Suspend the pellet in 310 µL of B-PER® II, Bacterial Protein Extraction Reagent by mixing up and down with the pipette.
12. Transfer 100 µL of the bacterial extraction to each tube of Reagent A, B, and C.
13. Incubate the tubes in a heat block at 37°C for 30 min.
14. Examine the color of the reagents in each tube

Expected Results



Documentation of Results
Results should be documented on the QC log rather than in the computer.

PROVIDENCE Sacred Heart Medical Center & Children's Hospital

Rapid HIV Kit (Determine HIV1&2 Ag/Ab Combo)

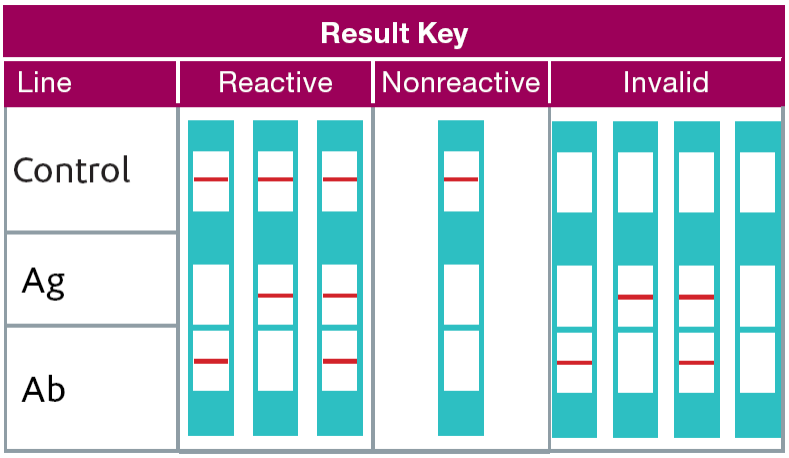
Frequency of QC Testing
External controls are run with each new lot or shipment when received and every 30 d, while in use. Internal controls must be read and documented for each test.

Controls
Alere Determine™ HIV-1/2 Ag/Ab Combo Controls are available, separate from the kit, for use with the assay. Control material should be stored at 2-8°C and used up to the expiration date.

Procedure
External Quality Control
1. Use one test device for each of the four controls.
2. Using a pipette, apply 50 µL of control to the sample pad (marked by the arrow symbol). Do not add chase buffer.
3. Read the test result between 20 and 30 min after the addition of the sample. Do not read test results after 30 min.

Internal Quality Control
A pink/red colored line appearing in the control area is considered an internal positive procedural control, indicating proper performance and reactive reagents. A clear background in the results area is considered an internal negative control. If the test has been performed correctly and reagents are working properly, the background will clear to give a discernible result.

Expected Results



Nonreactive Control (One Line – Control Line)
HIV-1 p24 Antigen Control (Two Lines - Control and Ag Line)
HIV-1 Reactive Control (Two Lines - Control and Ab Line)
HIV-2 Reactive Control (Two Lines - Control and Ab Line)

Documenting QC
Record the internal control on the test log and external QC in LIS

Computer Entry of Results
Function: MQCE
Select: TESTQC
Category: UNSCHEDULED
Item Code: HVABAG
Results: OK

Entering New Lots
MFG Code: ALERE