

STEC Testing Options with ASSURANCE GDS®

The **Assurance GDS®** pathogen detection system is uniquely suited to help food processors and testing labs meet the latest food safety challenges associated with accurate detection of ***E. coli* O157:H7** as well as the **Top 6 Non-O157 Shiga Toxigenic *E. coli* (Top STEC)**.

The versatile collection of **Assurance GDS STEC assays** incorporate 3 levels of specificity, including proprietary **PickPen® Immunomagnetic Separation (IMS)** technology and PCR analysis utilizing highly specific DNA primers and probes to ensure fast and accurate results for this elusive group of pathogenic *E. coli*.



Flexible Building - Blocks:

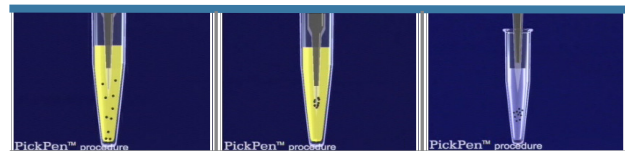
The comprehensive collection of Assurance GDS STEC assays offers unparalleled flexibility, allowing organizations to assemble custom testing strategies to fit their specific food safety program needs for the detection and confirmation of *E. coli* O157:H7 and the Top 6 non-O157 serogroups of STEC (O26, O45, O103, O111, O121, and O145).

Advantages of PickPen IMS

The patented PickPen IMS-based sample preparation procedure utilized by Assurance GDS helps eliminate false positives caused by non-target O-groups of *E. coli*.

Because there are over 200 serotypes of STEC that contain the *eae* and/or *stx* genes, Top STEC detection methods that do not select for the 6 specific target O-groups prior to PCR analysis can produce many times the number of presumptive test results that do not culturally confirm.

With the Assurance GDS PickPen IMS procedure, magnetic particles coated with antibodies specific to the Top STEC O-groups are combined with the enriched sample. If present, *E. coli* belonging to the target O-groups bind to the antibodies attached to the particles. The PickPen device collects and removes the particles with the bound *E. coli*, separating them from the non-target O-groups and helping to ensure detection of the gene targets is limited to the desired O-groups of *E. coli*.



Antibody-coated magnetic particles are combined with an aliquot of enriched sample.

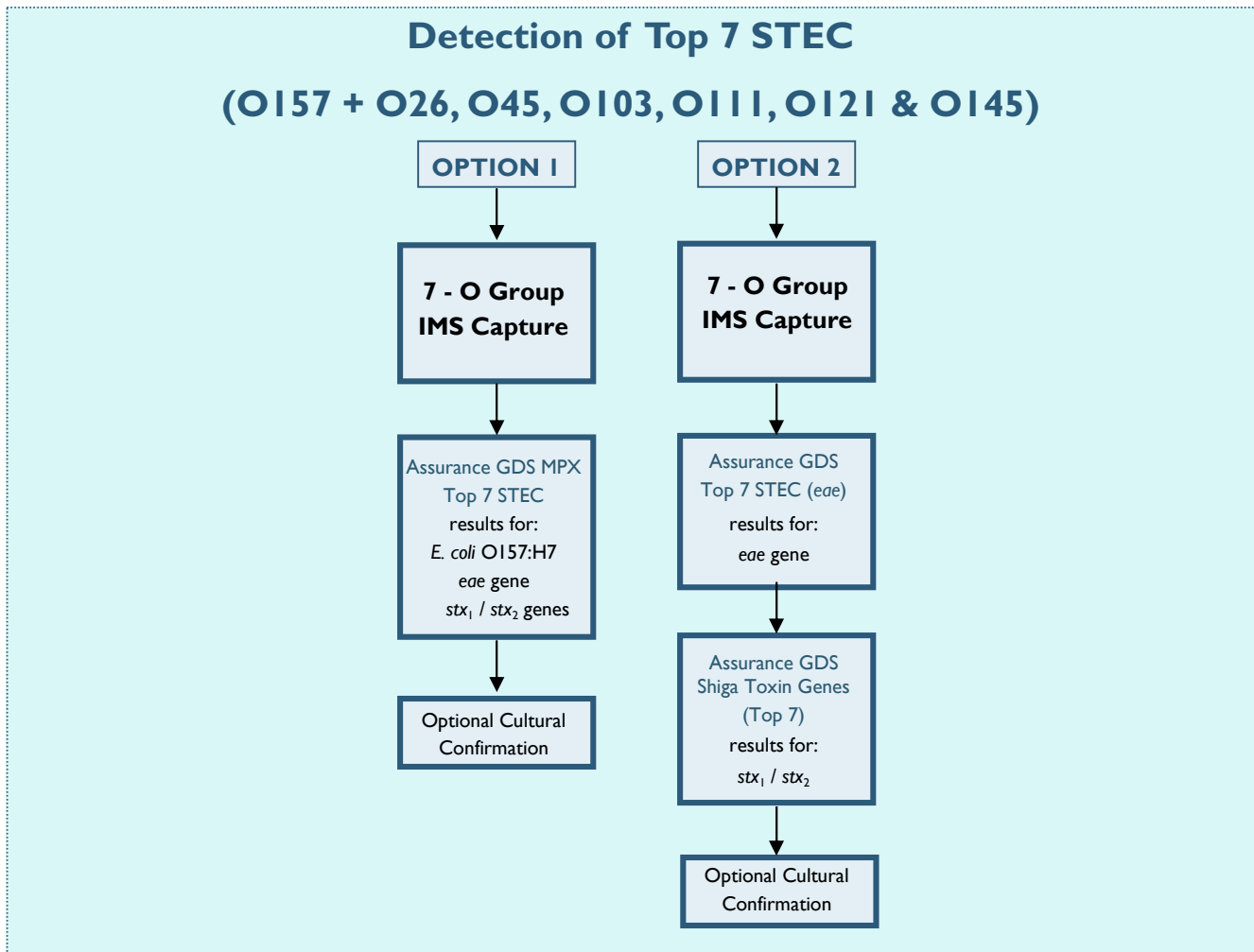
Intrasolution PickPen magnet captures particles and bound organism.

Particles are extracted, resuspended in a clean buffer and transferred to the Assurance GDS detection system.

BIOCONTROL

Results. Right now.

Multiple Testing Strategies with Assurance GDS STEC Assays



Top 7 O-Group IMS capture options for the simultaneous detection of *E. coli* O157:H7 and the Top 6 non-O157 STEC

MPX Top 7 STEC

Assurance GDS MPX Top 7 STEC provides definitive positive / negative results for *E. coli* O157:H7 and the Top 6 non-O157 STEC (O26, O45, O103, O111, O121, and O145) in a single assay. Following IMS capture of the Top 7 O-groups, Top STEC results are determined by the presence of the *eae* and *stx*₁ and *stx*₂ genes, while *E. coli* O157:H7 results are based on the same proven gene target found in the Assurance GDS *E. coli* O157:H7 kit, utilized extensively throughout the industry.

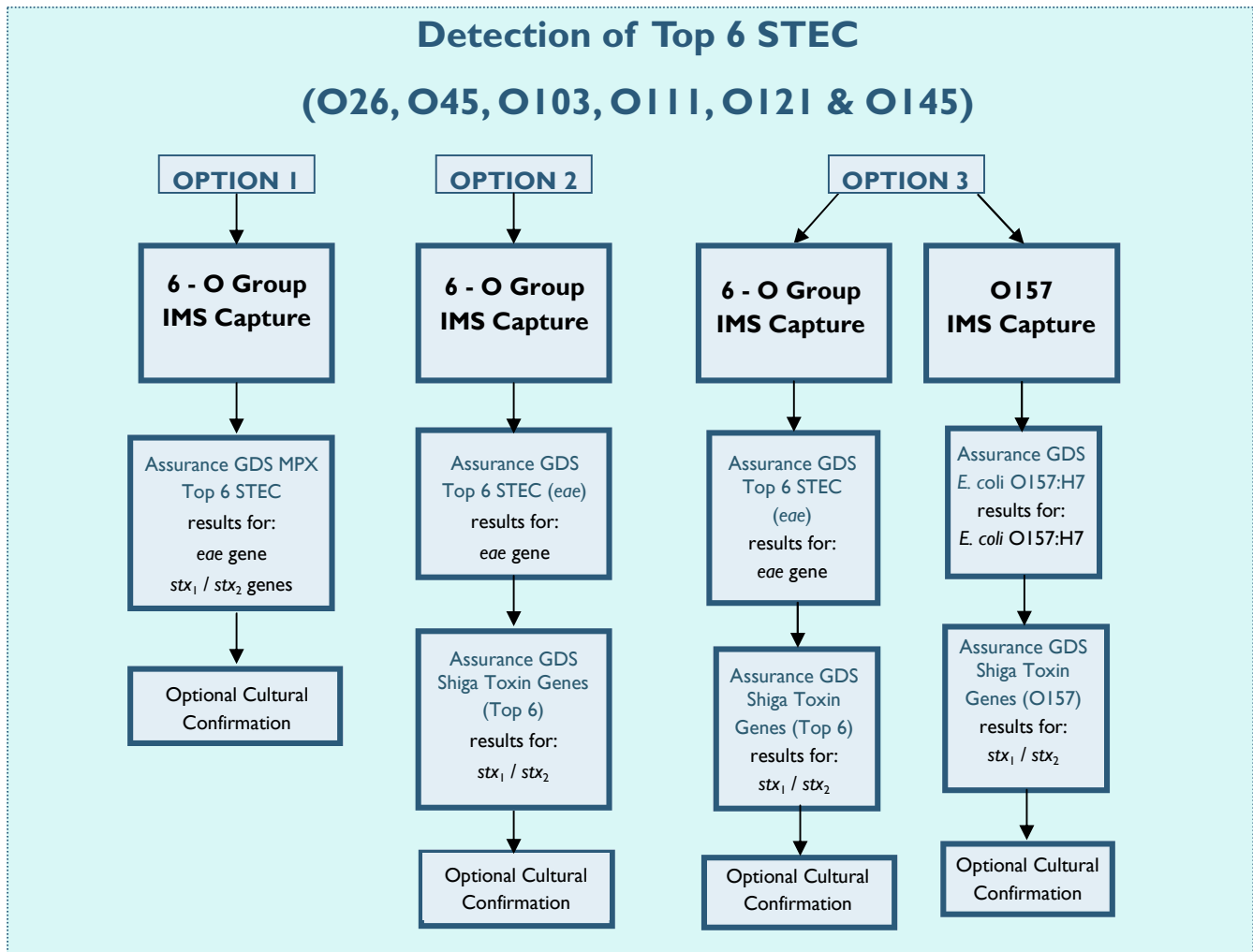
Top 7 STEC (*eae*)

Assurance GDS Top 7 STEC (*eae*) detects the presence of the *eae* gene in any of the Top 7 STEC O-groups (O26, O45, O103, O111, O121, O145 and O157). When combined with Assurance GDS Shiga Toxin Genes (Top 7) these assays detect the presence of the Top 7 STEC, including *E. coli* O157:H7 with the added benefit of providing Shiga Toxin gene results only for samples that have tested *eae* positive.

Shiga Toxin Genes (Top 7)

Assurance GDS Shiga Toxin Genes (Top 7) detects and differentiates *stx*₁ and *stx*₂ specifically from the Top 7 STEC O-groups (O26, O45, O103, O111, O121, O145 and O157). It can be used as a secondary confirmation assay for Assurance GDS Top 7 STEC (*eae*) or as a primary screen for the presence of the Top 7 STEC.

Multiple Testing Strategies with Assurance GDS STEC Assays



Top 6 O-Group IMS capture options to maintain separate methods for the detection of *E. coli* O157:H7 and the Top 6 non-O157

MPX Top 6 STEC

Following IMS capture of the Top 6 O-groups (O26, O45, O103, O111, O121, and O145), Assurance GDS MPX Top 6 STEC provides definitive positive / negative results for the Top 6 non-O157 STEC based on the presence of the *eae* and *stx*₁ and *stx*₂ genes. Results of each individual gene target and an overall Top STEC result are automatically provided, requiring no user-interpretation of curves.

Top 6 STEC (*eae*)

Assurance GDS Top 6 STEC (*eae*) detects the presence of the *eae* gene in any of the Top 6 non-O157 STEC O-groups (O26, O45, O103, O111, O121, and O145). When combined with Assurance GDS Shiga Toxin Genes (Top 6) these assays detect the presence of the Top 6 non-O157 STEC, with the added benefit of providing Shiga Toxin gene results only for samples that have tested *eae* positive.

Shiga Toxin Genes (Top 6)

Assurance GDS Shiga Toxin Genes (Top 6) detects and differentiates *stx*₁ and *stx*₂ specifically from the Top 6 non-O157 STEC O-groups (O26, O45, O103, O111, O121, and O145). It can be used as a secondary confirmation assay for Assurance GDS Top 6 STEC (*eae*) or as a primary screen for the presence of the Top 6 non-O157 STEC.

E. coli O157:H7

Used extensively throughout the industry, Assurance GDS *E. coli* O157:H7 provides fast and accurate results specifically for *E. coli* O157:H7. Results are available in just 10 hours for 375g samples and as fast as 8 hours for 25g samples.

A S S U R A N C E

G D S[®]

Genetic Detection System

Speed

The centrifugal air-exchange design of the Assurance GDS Rotor-Gene[®] makes it over 100% faster than conventional thermal cyclers

Simplicity

From start to finish, BioControl has designed Assurance GDS to be simple, flexible and easy to run

Specificity

Assurance GDS incorporates 3 levels of specificity including PickPen[®] IMS and patented primers and probes to ensure greater accuracy

Sensitivity

Assurance GDS delivers a greater amount of quality DNA for analysis, ensuring a high degree of sensitivity



ORDERING INFORMATION

Assurance GDS Tests	Part No.	Qty:
Assurance GDS MPX Top 7 STEC	61015-100	100
Assurance GDS MPX Top 6 STEC	61016-100	100
Assurance GDS Top 7 STEC (eae)	61017-100	100
Assurance GDS Top 6 STEC (eae)	61013-100	100
Assurance GDS Shiga Toxin Genes (Top 7)	61018-100	100
Assurance GDS Shiga Toxin Genes (Top 6)	61014-100	100
Assurance GDS Shiga Toxin Genes (O157)	61005-100	100
Assurance GDS E. coli O157:H7	61007-100	100

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ISO 9001, ISO 13485

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