



Validation of alternative analysis methods

NF102 – Application to the food industry

Certificate

Certificate No.: **3M 01/18-05/17**

Validation decision dated: 18-05-2017

Expiry date: 18-05-2021

The Company:

3M Health Care
Food Safety Department
2501 Hudson Road, Building 275 5W 05
Saint Paul, MN 55144-IWO - United States

Is authorized to affix the NF VALIDATION mark on the alternative analysis method cited below, in accordance with the NF VALIDATION general rules and the certification rules NF102 - Validation of alternative analysis methods (Application to the food industry):

3M™ Molecular Detection Assay 2 - *E. coli* O157 (including H7)

Validated for the detection of *Escherichia coli* O157

Technical sheet
reference's

34-8720-4565-2

This decision attests that the alternative analysis method has been assessed by AFNOR Certification and found to conform to the standards cited in page 2/2 and complementary requirements, as specified in the certification reference document. The principal certified characteristics are the "analytical performances" as defined in the associated validation study summarized report (sensitivity, relative level of detection...), available on the certification dedicated website <http://nf-validation.org/en>.

This certificate supersedes all previous certificates (last version dated 13-09-2017). This NF VALIDATION certificate, included 2 pages, is valid until 18th May 2021. It is subject to the results obtained upon regular controls carried out by AFNOR Certification. Appropriate decision is made by AFNOR Certification in accordance with the NF VALIDATION general rules and certification rules NF102 - Validation of alternative analysis methods (Application to the food industry).




Managing Director
Franck LEBEUGLE

Issue dated 21/12/2017

Page 1/2

The alternative analysis method:

3M™ Molecular Detection Assay 2 - *E. coli* O157 (including H7)

Validated for the detection of *Escherichia coli* O157

Manufactured by:

3M Columbia Plant
5400 Paris Road
Columbia, Missouri 65202 - United States

Has been certified according to the reference documents and the application scope specified here after:

Validation protocol	NF EN ISO 16140-2 (September 2016): Microbiology of the food chain. Method validation - Part 2: Protocol for the validation of alternative (proprietary) methods against a reference method.
Reference method(s)	NF EN ISO 16654 (July 2001): Microbiology of food and animal feeding stuffs. Horizontal method for the detection of <i>Escherichia coli</i> O157.
Scope	Raw beef meats, raw dairy products, raw fruits and vegetables.
Restriction(s)	None.
Warning	None.
Other informations	The scope includes the use of the 3M™ Molecular Detection instrument and its software version 2.2 or later versions.

Please send any queries concerning the performances of the certified alternative method to AFNOR Certification.

You may download the validation study summarized report on <http://nf-validation.afnor.org/en>.