



Validation of alternative analysis methods

NF102 – Application to the food industry

Certificate

Certificate No.: **SDC 42/02-12/24**

Validation decision dated: **19-12-2024**

Expiry date: **19-12-2028**

The Company:

Shimadzu Diagnostics Corporation

20F Ueno Frontier Tower,
3-24-6 UENO, TAITO-KU, TOKYO,
110-8736 JAPAN

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):

CompactDry™ EC (*E. coli*)

Validated for the enumeration of *Escherichia coli*

Technical sheet
reference's

SDE-IFU-EC-2024-V05

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 NF VALIDATION certificate, included 2 pages, is valid until **December 19th, 2028**. 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
Julien NIZRI

Issue dated 19/12/2024

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The alternative analysis method:

CompactDry™ EC (*E. coli*)

Validated for the enumeration of *Escherichia coli*

Manufactured by:

Shimadzu Diagnostics Corporation
1075-2, Hokunammoro, Yuki-shi,
Ibaraki 307-0036
JAPAN

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 ISO 16649-2 (July 2001): Microbiology of food and animal feeding stuffs - Horizontal method for the enumeration of B-glucuronidase-positive <i>Escherichia coli</i> - Part 2 : colony-count technique at 44 °C using 5-bromo-4-chloro-3-indolyl B-D-glucuronate.
Scope	All human food products (by performing validation assays on a broad range of foods) and industrial production environmental samples.
Restriction(s)	None.
Warning	None.
Other information	Non applicable.

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>.

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