June 4, 2025

NG Biotech
% Anna Klavins
Director of Technical Services and R&D
Hardy Diagnostics
1430 West McCoy Lane
Santa Maria, California 93455

Re: K243499
Trade/Device Name: NG-Test CTX-M MULTI
Regulation Number: 21 CFR 866.1640
Regulation Name: Antimicrobial Susceptibility Test Powder
Regulatory Class: Class II
Product Code: PTJ
Dated: May 8, 2025
Received: May 9, 2025

Dear Anna Klavins:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Ribhi Shawar -S

Ribhi Shawar, Ph.D. (ABMM)
Chief,
General Bacteriology and Antimicrobial Susceptibility Branch
Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K243499

Device Name
NG-Test® CTX-M MULTI

Indications for Use *(Describe)*
NG-Test® CTX-M MULTI is an *in vitro* rapid and visual immunochromatographic assay for the qualitative detection of CTX-M enzymes (groups 1, 2, 8, 9, and 25) from pure colonies of Enterobacterales suspected of ESBL production when grown on the following media:
• 5% sheep blood agar or MacConkey agar (16-24 hours)
• HardyCHROM™ ESBL agar (18-24 hours)
The NG-Test® CTX-M MULTI is intended as an aid for infection control in the detection of CTX-M enzymes-producing organisms (Enterobacterales) in healthcare settings. NG-Test® CTX-M MULTI is not intended to guide or monitor treatment. A positive or negative NG- Test® CTX-M MULTI test result does not rule out the presence of other mechanisms of antibiotic resistance. NG-Test® CTX-M MULTI should be used in conjunction with other laboratory tests including phenotypic antimicrobial susceptibility testing.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

November 11th, 2024

The following information is provided in accordance with 21 CFR 807.92 for the Premarket 510(k) Summary:

I. General Information

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II. Device Information

Device Trade Name: NG-Test® CTX-M MULTI
Common Name: NG-Test® CTX-M MULTI
Classification Name: Antimicrobial Susceptibility Test Powder
Regulation Number: 21 CFR 866.1640
Regulatory Class: II
Product Code: PTJ

III. Predicate Device

NG-Test CARBA 5 (K191889)

IV. Device Description

NG-Test® CTX-M MULTI is an *in vitro* rapid and visual immunochromatographic assay for the qualitative detection of CTX-M enzymes (groups 1, 2, 8, 9, and 25) from pure colonies of Enterobacterales suspected of ESBL production after culturing on agar and processed in an extraction buffer. The device consists of a sample port, sample and conjugate pad, and nitrocellulose test strip, which are contained within a plastic cassette, in addition to reagents for liquid extraction. The result can be read 15 minutes after adding the sample to the sample well. A positive result on the NG-Test® CTX-M MULTI occurs when two red lines appear, one on the

control (C) region and one on the test (T) region. A negative result occurs when only the control line is observed and indicates the sample does not contain any target CTX-M enzymes, or the CTX-M enzymes are present at a non-detectable level. If the control line does not appear, the test result is invalid.

Monoclonal antibodies that recognize the five major CTX-M groups are immobilized on a nitrocellulose membrane. Free monoclonal antibodies are present in the conjugate pad and labeled with colloidal gold. Upon addition of the processed sample to the sample pad, the capillary action of the nitrocellulose draws the sample through the mobile antibodies in the conjugate pad and the immobile antibodies on the test strip. The immobilized control antibodies capture any mobile antibodies that do not bind to the test line.

V. Intended Use/Indications of Use

NG-Test® CTX-M MULTI is an *in vitro* rapid and visual immunochromatographic assay for the qualitative detection of CTX-M enzymes (groups 1, 2, 8, 9, and 25) from pure colonies of Enterobacterales suspected of ESBL production when grown on the following media:

- 5% sheep blood agar or MacConkey agar (16-24 hours)
- HardyCHROM™ ESBL agar (18-24 hours)

The NG-Test® CTX-M MULTI is intended as an aid for infection control in the detection of CTX-M enzymes-producing organisms (Enterobacterales) in healthcare settings. NG-Test® CTX-M MULTI is not intended to guide or monitor treatment. A positive or negative NG-Test® CTX-M MULTI test result does not rule out the presence of other mechanisms of antibiotic resistance. NG-Test® CTX-M MULTI should be used in conjunction with other laboratory tests including phenotypic antimicrobial susceptibility testing.

VI. Substantial Equivalence Comparison

The following table demonstrates the substantial equivalence comparison of NG-Test® CTX-M MULTI.

	Device	**Predicate**
	NG-Test® CTX-M MULTI	**NG-Test® CARBA 5**
510(k) Details	N/A Product Code PTJ 21 CFR 866.1640 "Antimicrobial Susceptibility Test Powder" Class II Microbiology	K191889 Product Code PTJ 21 CFR 866.1640 "Antimicrobial Susceptibility Test Powder" Class II Microbiology
Intended Use	NG-Test® CTX-M MULTI is an *in vitro* rapid and visual immunochromatographic assay for the qualitative detection of CTX-M enzymes (groups 1, 2, 8, 9, and 25)	NG-Test® CARBA 5 is an *in vitro* rapid and visual multiplex immunochromatographic assay for the qualitative detection and differentiation of five common carbapenemases (KPC,

	from pure colonies of Enterobacterales suspected of ESBL production when grown on the following media: • 5% sheep blood agar or MacConkey agar (16-24 hours). • HardyCHROM™ ESBL agar (18-24 hours). The NG-Test® CTX-M MULTI is intended as an aid for infection control in the detection of CTX-M enzymes-producing organisms (Enterobacterales) in healthcare settings. NG-Test® CTX-M MULTI is not intended to guide or monitor treatment. A positive or negative NG-Test® CTX-M MULTI test result does not rule out the presence of other mechanisms of antibiotic resistance. NG-Test® CTX-M MULTI should be used in conjunction with other laboratory tests including phenotypic antimicrobial susceptibility testing.	OXA-48-like, VIM, IMP, and NDM) from carbapenem non-susceptible pure bacterial colonies when grown on the following media: • 5% sheep blood agar or MacConkey agar (16-24 hours) for testing Enterobacterales (formerly *Enterobacteriaceae*) and *Pseudomonas aeruginosa*. • HardyCHROM™ CRE agar (18-24 hours) for testing *E. coli* and KES (*Klebsiella aerogenes*, *Klebsiella oxytoca*, *Klebsiella pneumoniae*, *Enterobacter cloacae* complex and *Serratia marcescens*). The NG-Test® CARBA 5 is intended as an aid for infection control in the detection of carbapenemase-producing Enterobacterales and *Pseudomonas aeruginosa* in healthcare settings. NG-Test® CARBA 5 is not intended to guide or monitor treatment for carbapenem non-susceptible bacterial infections. A positive or negative NG-Test® CARBA 5 test result does not rule out the presence of other mechanisms of antibiotic resistance. NG-Test® CARBA 5 should be used in conjunction with other laboratory tests including phenotypic antimicrobial susceptibility testing.
Interpretation	Visual	Same
Controls	Built-in procedural control in every test strip	Same
Intended Culture Media	5% sheep blood agar, MacConkey agar	Same
Sample Type	Bacterial colonies	Same
Inoculum Preparation	By touching 3 colonies with a 1 µL loop	Same
General Device Characteristic Differences		
Intended Culture Media	HardyCHROM™ ESBL agar	HardyCHROM™ CRE agar
Analyte	CTX-M enzymes	Carbapenemase enzymes (KPC, OXA-48-like, VIM, IMP, NDM)

VII. Performance Data

The performance of the NG-Test® CTX-M MULTI was evaluated at three geographically diverse hospitals with prospectively-collected and stock bacterial isolates of Enterobacterales. The NG-Test® CTX-M MULTI performance was compared to reference method PCR and antimicrobial susceptibility testing (AST) according to the breakpoints described in the CLSI M100, 34th edition. The identification (ID) and AST of organisms was performed using FDA-cleared ID and AST systems. NG-Test® CTX-M MULTI quality control was performed daily in parallel with each day of testing. A total of 309 Enterobacterales were tested using phenotypic AST (disk diffusion and MIC) and reference method PCR. Isolates with a positive PCR result were also sequenced to determine the CTX-M variant. A positive reaction in the comparator method was defined as any Enterobacterales that produced a positive PCR result and was not susceptible to at least one of the antimicrobial agents. 308 isolates had concordant results between the NG-Test® CTX-M MULTI and reference method. One isolate of *Citrobacter amalonaticus* yielded a false-positive result.

The sensitivity for Enterobacterales from all sites combined for colonies tested on NG-Test® CTX-M MULTI from blood agar and MacConkey agar was 100.0% (95% confidence interval [CI]: 97.5% - 100.0%). The specificity was 99.4% (95% CI: 96.5% - 99.9%).

The sensitivity and specificity from the clinical study are summarized in Table 1.

Table 1. Comparison of NG-Test® CTX-M MULTI (Blood and MacConkey Agar) to Comparator Method – Study Device vs. Reference Method

Total Isolates	TP	FP[1]	FN	TN	Sensitivity	Low 95%	High 95%	Specificity	Low 95%	High 95%
309	151	1	0	157	100.0	97.5	100.0	99.4	96.5	99.9

[1]One isolate of *Citrobacter amalonaticus* was positive on NG-Test® CTX-M MULTI, not susceptible to at least one antimicrobial tested, and negative for $bla_{\text{CTX-M}}$ by PCR.

The CTX-M variants detected during the NG-Test® CTX-M MULTI clinical study are outlined in Table 2.

Table 2. Overall CTX-M Variants Detected by NG-Test® CTX-M MULTI in Clinical Study (Blood Agar and MacConkey Agar)

CTX-M Group	Overall Variants Detected in US Clinical Trial
1	CTX-M-1, -3, -15, -55, -178, -232, -V263A[1]
2	CTX-M-2
8	CTX-M-8
9	CTX-M-14, -24, -27, -65

[1]The CTX-M variant in this isolate features a V263A substitution (valine to alanine at position 263).

The clinical trial isolates used to evaluate the NG-Test® CTX-M MULTI device from blood agar and MacConkey agar at the clinical sites were also used to evaluate the performance of NG-Test® CTX-M MULTI from HardyCHROM™ ESBL (HC ESBL) agar. NG-Test® CTX-M MULTI quality control was performed daily in parallel with each day of testing.

A total of 193 clinical isolates that met HC ESBL agar claims were tested with the NG-Test® CTX-M MULTI device using colonies recovered from culture of seeded stool samples in accordance with HC ESBL agar claims. Among the tested Enterobacterales, 192 showed concordant results between the NG-Test® CTX-M MULTI and the reference method. One false-positive result was identified, corresponding to the same discrepant isolate from the testing with blood agar and MacConkey agar.

The sensitivity for Enterobacterales tested on the NG-Test® CTX-M MULTI from HC ESBL agar, processed with both types of stool specimens, was 100.0% (95% CI: 97.5% - 100.0%). The specificity was 97.7% (95% CI: 87.9% - 99.6%).

The sensitivity and specificity from the seeded study are summarized in Table 3.

Table 3. Seeded Study Comparison of NG-Test® CTX-M MULTI (HC ESBL Agar – Raw and C&S Stool) to Comparator Method – Study Device vs. Reference Method

Total Isolates	TP	FP[1]	FN	TN	Sensitivity	Low 95%	High 95%	Specificity	Low 95%	High 95%
193	150	1	0	42	100.0	97.5	100.0	97.7	87.9[2]	99.6

[1]One isolate of *Citrobacter amalonaticus* was positive on NG-Test® CTX-M MULTI, not susceptible to at least one antimicrobial tested, and negative for *bla*$_{\text{CTX-M}}$ by PCR.
[2]Lower bound is below 90% due to lower quantity of CTX-M negative clinical isolates that meet HC ESBL agar claims. Additional CTX-M negative isolates were evaluated in the cross-reactivity study.

VIII. Analytical Reactivity

NG-Test® CTX-M MULTI was evaluated using 57 strains of Enterobacterales characterized to harbor CTX-M enzymes. Each organism was incubated for 16 to 24 hours on blood agar and MacConkey agar, and for 18 to 24 hours on HC ESBL agar at 35°C. Each isolate was tested in triplicate from each type of media, and results were read 15 minutes after inoculating the extraction buffer mixed with bacteria into the sample port. The percent agreement across all target organisms was 100% (57/57), 100% (57/57), and 100% (56/56) from blood, MacConkey, and HC ESBL agar, respectively.

Variants detected during the analytical reactivity study are outlined in Tables 4 and 5.

Table 4. Analytical Reactivity Summary of Tested Variants

Number of **strains** tested on blood and MacConkey agar	Number of **strains** tested on HC ESBL agar	**CTX-M Group**	Number of individual **variants** tested on blood and MacConkey agar	Number of individual **variants** tested on HC ESBL agar	**CTX-M Variants Tested**
57	56[1]	1	31	30	CTX-M-1, -3, -12, -15, -22, -30, -32, -55, -64, -79, -116
		2	5	5	CTX-M-2, -74, -75, -124
		8	2	2	CTX-M-40
		9	18	18	CTX-M-9, -9-like, -14, -14b, -24, -27, -38
		25	6	6	CTX-M-25, -100, -152, -160
		Total	62	61	

[1] One *P. mirabilis* strain with a characterized CTX-M-3 variant was susceptible to an antimicrobial agent in the HC ESBL formula, thus was not evaluated with NG-Test® CTX-M MULTI from HC ESBL.

Table 5. Analytical Reactivity Summary

Genus species	Number of **strains** tested on Blood and MacConkey agar	Number of **strains** tested on HardyCHROM™ ESBL agar	**CTX-M Variants Tested**
Citrobacter species	1	1	CTX-M-15
Enterobacter cloacae	9	9	CTX-M-9, -9-like, -15, -22, -30, -100
Escherichia coli	19	19	CTX-M-1, -2, -3, -14, -15, -24, -27, -40, -55, -79, -100, -116
Klebsiella oxytoca	5	5	CTX-M-14, -15, -22, -30, -75, -100
Klebsiella pneumoniae	14	14	CTX-M-3, -12, -14, -14b, -15, -22, -25, -38, -40, -64, -74, -124
Klebsiella variicola	1	1	CTX-M-152
Kluyvera ascorbata	1	1	CTX-M-124
Proteus mirabilis	6	5[1]	CTX-M-3, -15, -32, -79, -160
Serratia marcescens	1	1	CTX-M-15

[1] One *P. mirabilis* strain with a characterized CTX-M-3 variant was susceptible to an antimicrobial agent in the HC ESBL formula, thus was not evaluated with NG-Test® CTX-M MULTI from HC ESBL.

IX. Analytical Specificity

NG-Test® CTX-M MULTI was evaluated with 55 organisms that exhibit antimicrobial resistance mechanisms other than CTX-M and were not susceptible to third-generation cephalosporins (cefotaxime, ceftazidime, ceftriaxone, cefpodoxime) and other agents (aztreonam and cefoxitin) from blood and MacConkey agar. 50 organisms were evaluated from HC ESBL. Some of the antimicrobial resistance mechanisms included were TEM, SHV, VEB, ACT, CMY, DHA, FOX, MIR, ACC, VIM, KPC, IMP, NDM, and OXA. Each organism was incubated for 16 to 24 hours on blood agar and MacConkey agar, or for 18 to 24 hours on HC ESBL agar at 35°C. Each organism was tested from each type of media, and results were read 15 minutes after inoculating the extraction buffer mixed with bacteria into the sample port. No cross reactivity was observed, thus the percent agreement for all non-target organisms evaluated was 100% (55/55), 100% (55/55), and 100% (50/50) from blood, MacConkey, and HC ESBL agar, respectively.

X. Incubation Study

In order to confirm that the NG-Test® CTX-M MULTI consistently delivered accurate results over a range of incubation times, five strains were tested from blood agar and MacConkey agar every two hours between 16 to 24 hours of aerobic incubation at 35°C. Five strains were also tested from HC ESBL agar every two hours between 18 to 24 hours of aerobic incubation at 35°C. All organisms produced the expected result on NG-Test® CTX-M MULTI at every time point. Test results were read 15 minutes after inoculating the buffer mixed with bacteria into the sample port.

XI. Refrigeration Storage Study

In order to determine if a refrigerated organism culture (plate agar media with colonies) can be used with NG-Test® CTX-M MULTI, five strains were cultured on blood agar, MacConkey agar, and HC ESBL agar, and evaluated over time from refrigerated storage. Each strain was incubated on blood and MacConkey agar at 35°C, with initial tests performed after 16 to 24 hours of incubation (Day 0). Initial testing for cultures on HC ESBL agar was conducted after 18 to 24 hours of incubation. All organisms

produced the expected result on the NG-Test® CTX-M MULTI for each day of refrigeration for up to 3 days.

XII. Reproducibility

Prior to initiating the clinical study, a panel of 20 blinded isolates provided by Hardy Diagnostics was tested at three distinct study sites on five days to demonstrate reproducibility and document proficiency in the performance of NG-Test® CTX-M MULTI. A >95% agreement with known test results was required to proceed with the clinical study. The testing was done with one operator and two readers, blinded to each other's results, per site. NG-Test® CTX-M MULTI successfully detected all target CTX-M positive isolates (100%) on every day of the reproducibility study.

XIII. Conclusions

The analytical and clinical data presented in this submission demonstrate that NG-Test® CTX-M MULTI is substantially equivalent to the predicate device.