



July 9th, 2025

Abbott Laboratories
Weijie Jiao
Principal Regulatory Affairs Specialist
100 Abbott Park Road
Dept. C2D8, Building AP08/A
Abbott Park, Illinois 60064

Re: K243500
Trade/Device Name: ARCHITECT iGentamicin
Regulation Number: 21 CFR 862.3450
Regulation Name: Gentamicin Test System
Regulatory Class: Class II
Product Code: LCD
Dated: June 6, 2025
Received: June 9, 2025

Dear Weijie Jiao:

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](https://www.fda.gov/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,

JOSEPH A.
KOTAREK -S

Digitally signed by
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Joseph Kotarek
Branch Chief for Toxicology
Division of Chemistry and Toxicology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K243500

Device Name
ARCHITECT iGentamicin

Indications for Use (Describe)

The ARCHITECT iGentamicin assay is an in vitro chemiluminescent microparticle immunoassay (CMIA) for the quantitative determination of gentamicin, an antibiotic drug, in human serum or plasma on the ARCHITECT iSystem with STAT protocol capability. The measurements obtained are used in the diagnosis and treatment of gentamicin overdose and in monitoring levels of gentamicin to help ensure appropriate therapy.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

This summary of the 510(k) safety and effectiveness information is being submitted in accordance with the requirements of the Federal Food, Drug, and Cosmetic Act and 21 CFR 807.92.

I. 510(k) Number

k243500

II. Applicant Name

Date summary prepared: December 11, 2024

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III. Device Name

ARCHITECT iGentamicin

Reagents

Trade Name: ARCHITECT iGentamicin
Device Classification: Class II
Classification Name: Gentamicin test system
Governing Regulation: 862.3450
Product Code: LCD

IV. Predicate Device

ARCHITECT iGentamicin (k102699)

V. Intended Use of the Device

The ARCHITECT iGentamicin assay is an *in vitro* chemiluminescent microparticle immunoassay (CMIA) for the quantitative determination of gentamicin, an antibiotic drug, in human serum or plasma on the ARCHITECT iSystem with STAT protocol capability. The measurements obtained are used in the diagnosis and treatment of gentamicin overdose and in monitoring levels of gentamicin to help ensure appropriate therapy.

VI. Description of Device

The ARCHITECT iGentamicin Reagent Kit contains:

- **Microparticles:** 1 bottle (7.11 mL per 100 test cartridge). Anti-gentamicin (mouse, monoclonal) coated microparticles in TRIS buffer with protein (bovine) stabilizer. Minimum concentration: 0.13% solids. Preservatives: ProClin 950 and sodium azide.
- **Conjugate:** 1 bottle (11.75 mL per 100 test cartridge). Gentamicin acridinium-labeled conjugate in MES buffer. Minimum concentration: 3 nM. Preservative: ProClin 300.

Principles of the Procedure

The ARCHITECT iGentamicin assay is an automated one-step immunoassay for the quantitative determination of gentamicin in human serum or plasma using CMIA technology with flexible assay protocols, referred to as Chemiflex.

1. Sample, anti-gentamicin coated paramagnetic microparticles, and gentamicin acridinium-labeled conjugate are combined to create a reaction mixture. The anti-gentamicin coated microparticles bind to the gentamicin present in the sample and to the acridinium-labeled conjugate.
2. After washing, Pre-Trigger and Trigger Solutions are added to the reaction mixture.
3. The resulting chemiluminescent reaction is measured as relative light units (RLUs). There is an indirect relationship between the amount of gentamicin in the sample and the RLUs detected by the ARCHITECT iSystem optics.

VII. Comparison of Technological Characteristics

The ARCHITECT iGentamicin assay utilizes a CMIA methodology for the quantitative determination of gentamicin, an antibiotic drug, and is intended for use on the ARCHITECT iSystem with STAT protocol capability.

The similarities and differences between the subject device and the predicate device are presented in the following table.

Characteristics	Predicate Device: ARCHITECT iGentamicin List No. 1P31-25 (k102699)	Subject Device: ARCHITECT iGentamicin List No. 1P31-27
General Device Characteristic Similarities		
Intended Use and Indications for Use	The ARCHITECT iGentamicin assay is an <i>in vitro</i> chemiluminescent microparticle immunoassay (CMIA) for the quantitative determination of gentamicin, an antibiotic drug, in human serum or plasma on the ARCHITECT iSystem with STAT protocol capability. The measurements obtained are used in the diagnosis and treatment of gentamicin overdose and in monitoring levels of gentamicin to help ensure appropriate therapy.	Same
Measurand	Gentamicin	Same
Specimen Type	Human serum or plasma	Same
Instrument Platform	ARCHITECT iSystem	Same
Assay Technology	CMIA	Same
Measuring Interval (Reportable Range) (µg/mL)	0.3 to 10.0	Same
Reagent Packaging Configuration	100 Tests: 1 bottle (7.11 mL) Microparticles 1 bottle (11.75 mL) Conjugate	Same

Characteristics	Predicate Device: ARCHITECT iGentamicin List No. 1P31-25 (k102699)	Subject Device: ARCHITECT iGentamicin List No. 1P31-27
General Device Characteristic Differences		
Reagent Formulation	Microparticle % solids concentration: 0.20%	Microparticle % solids concentration: 0.13%
	Conjugate tracer concentration: 4 ng/mL	Conjugate tracer concentration: 3.4 ng/mL
	Detergent in microparticle and conjugate diluents: Triton X-100	Detergent in microparticle and conjugate diluents: Tergitol 15-S-9
	Solvent for conjugate tracer stock: Dimethylformamide (DMF)	Solvent for conjugate tracer stock: Dimethyl sulfoxide (DMSO)

VIII. Performance Summary

A. Within-Laboratory Precision

A study was performed based on guidance from Clinical and Laboratory Standards Institute (CLSI) EP05-A3*. Within-Laboratory precision ranged from 3.7% to 6.0 %CV for samples from 2 to 10 µg/mL gentamicin and from 3.1% to 3.7 %CV (0.010 to 0.055 SD) for samples below 2 µg/mL gentamicin.

B. Accuracy by Recovery (Spiked Recovery)

A study was performed based on guidance from CLSI EP34, 1st ed[†]. The mean percent recovery was 104.6%. The 95% confidence interval (CI) was from 101.5% to 107.6%.

C. Limit of Blank (LoB), Limit of Detection (LoD), and Limit of Quantitation (LoQ)

A study was performed based on guidance from CLSI EP17-A2[‡]. LoB was determined to be 0.00 µg/mL (same as predicate device), LoD was determined to be 0.01 µg/mL (lower than predicate device), and the maximum observed LoQ was 0.20 µg/mL (same as predicate device).

D. Linear Range

A study was performed based on guidance from CLSI EP06, 2nd ed[§]. The observed deviation from linearity ranged from -1.7% to 6.0% for samples between 1 and 10 µg/mL. The observed deviation from linearity ranged from -8.2% to 1.5% for samples below 1 µg/mL. Results for all 3 sample sets demonstrated acceptable linear performance across the target concentration range of 0.3 to 10.0 µg/mL.

* Clinical and Laboratory Standards Institute (CLSI). *Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline—Third Edition*. CLSI Document EP05-A3. Wayne, PA: CLSI; 2014.

† Clinical and Laboratory Standards Institute (CLSI). *Establishing and Verifying an Extended Measuring Interval Through Specimen Dilution and Spiking*. 1st ed. CLSI Guideline EP34. Wayne, PA: CLSI; 2018.

‡ Clinical and Laboratory Standards Institute (CLSI). *Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline—Second Edition*. CLSI Document EP17-A2. Wayne, PA: CLSI; 2012.

§ Clinical and Laboratory Standards Institute (CLSI). *Evaluation of the Linearity of Quantitative Measurement Procedures*. 2nd ed. CLSI Document EP06. Wayne, PA: CLSI; 2020.

E. Interference

1. Potentially Interfering Endogenous Substances

A study was performed based on guidance from CLSI EP07, 3rd ed^{*}. Two levels of gentamicin were tested: 2.5 and 7.5 µg/mL. The spiked samples were compared to the control samples. For all interferents, the difference in measured concentration of gentamicin ranged from -1.3% to 3.3%. The 95% CI around the % difference between test and reference samples ranged from -4.4% to 6.8%.

2. Potentially Interfering Clinical Conditions

A study was performed based on guidance from CLSI EP07, 3rd ed.^{*} (section 5) and CLSI EP34, 1st ed[†]. Normal human serum pool and samples containing the clinical conditions were spiked at two levels of gentamicin (2.5 and 7.0 µg/mL). Gentamicin concentrations of the spiked samples were compared to the samples without gentamicin. For all interferents, the mean % recovery ranged from 97.1% to 99.8%. The 95% CI around the % recovery ranged from 92.3% to 106.1%.

3. Potentially Interfering Drugs

A study was performed based on guidance from CLSI EP07, 3rd ed.^{*} and CLSI EP37, 1st ed[‡]. Potentially interfering drugs were tested for cross-reactivity or interference in samples containing 0 µg/mL, 2.5 µg/mL, and 7.0 µg/mL gentamicin. The % difference between the mean concentrations of the test sample and the reference sample ranged from -8.7% to 8.1% with the following exceptions.

For tobramycin, the mean % difference was 9.6% at 2.5 µg/mL and 11.9% at 7.0 µg/mL gentamicin. The result is included in the reagent package insert. The

^{*} Clinical and Laboratory Standards Institute (CLSI). *Interference Testing in Clinical Chemistry*. 3rd ed. CLSI Guideline EP07. Wayne, PA: CLSI; 2018.

[†] Clinical and Laboratory Standards Institute (CLSI). *Establishing and Verifying an Extended Measuring Interval Through Specimen Dilution and Spiking*. 1st ed. CLSI Guideline EP34. Wayne, PA: CLSI; 2018.

[‡] Clinical and Laboratory Standards Institute (CLSI). *Supplemental Tables for Interference Testing in Clinical Chemistry*. 1st ed. CLSI Guideline EP37. Wayne, PA: CLSI; 2018.

predicate results in the reagent package insert are 13.1% at 2.5 µg/mL and 13.8% at 7.0 µg/mL. Tobramycin will remain in the limitations of the reagent package insert.

For neomycin, netilmicin, and sisomicin, the 95% CI results exceeded ± 20% for at least one of the concentration levels tested. These interferents are included in the limitations of the reagent package insert.

F. Method Comparison

A study was performed based on guidance from CLSI EP09-A3.* using a Passing- Bablok regression method to compare the subject device to the predicate device (ARCHITECT iGentamicin [k102699]). The results are summarized in the table below.

Lot	N	Subject Device (Y) (µg/mL)		Predicate Device (X) (µg/mL)		Correlation Coefficient (r)		Regression Method	Intercept (µg/mL)		Slope	
		Min	Max	Min	Max	r	95% CI		Estimate	95% CI	Estimate	95% CI
1	98	0.45	9.98	0.48	9.27	1.00	(0.99, 1.00)	Passing-Bablok	-0.10	(-0.17, -0.03)	1.05	(1.03, 1.07)
2	39	0.46	9.40	0.48	9.91	0.99	(0.99, 1.00)	Passing-Bablok	0.05	(-0.05, 0.16)	1.00	(0.96, 1.03)
3	39	0.62	9.90	0.63	9.91	1.00	(1.00, 1.00)	Passing-Bablok	-0.02	(-0.08, 0.10)	1.03	(1.00, 1.06)

* Clinical and Laboratory Standards Institute (CLSI). *Measurement Procedure Comparison and Bias Estimation Using Patient Samples; Approved Guideline—Third Edition*. CLSI Document EP09, A3. Wayne, PA: CLSI; 2013.

G. Real Time Reagent Stability

Baseline testing was started within 1 month after reagents' manufacturing. Further testing was done on monthly basis for the first 3 months, then every 3 months until expiration date, and one month beyond expiry. Data generated confirmed that there is no impact to the stability of the subject device due to the proposed modifications, and the data continues to support 12 months dating. The regression analysis was performed per CLSI EP25-A*. The % shift at month 12 (claimed stability) ranged from -9.1% to 2.8%, and at month 13 ranged from -9.8% to 3.1% for all samples tested.

H. Reagent On-Board Drift

A study was performed based on guidance from CLSI EP25-A*. The results for samples tested are not susceptible to drift when the ARCHITECT iGentamicin design verification reagent lots are stored for a minimum of 30 days on board the ARCHITECT System. Results met the acceptance criteria with 1 calibration throughout the study for internal Westgard evaluation. For regression analysis, the % shift at 30 days ranged from -2.9% to 7.7% for samples between 2 to 10 µg/mL, and shift at 30 days ranged from -0.04 to 0.12 µg/mL for samples below 2 µg/mL for all three lots tested. The % shift at 32 days ranged from -3.1% to 8.2% for samples between 2 to 10 µg/mL, and shift at 32 days ranged from -0.04 to 0.12 µg/mL for samples below 2 µg/mL for all three lots tested.

IX. Conclusion

The results presented in this Special 510(k) demonstrate that the performance of the subject device (ARCHITECT iGentamicin) is substantially equivalent to the performance of the predicate device (ARCHITECT iGentamicin, k102699).

* Clinical and Laboratory Standards Institute (CLSI). *Evaluation of Stability of In Vitro Diagnostic Reagents; Approved Guideline*. CLSI Document EP25-A. Wayne, PA: CLSI; 2009.