February 21, 2023

Biokit, S.A.
Angels Roma
Regulatory Affairs & Design Quality Director
Av. Can Montcau, 7
Llica d'Amunt, Barcelona 08186
Spain

Re: K214068
Trade/Device Name: Quantia IgE
Regulation Number: 21 CFR 866.5510
Regulation Name: Immunoglobulins A, G, M, D, And E Immunological Test System
Regulatory Class: Class II
Product Code: DGC
Dated: October 28, 2022
Received: October 31, 2022

Dear Angels Roma:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

Ying Mao -S

Ying Mao, Ph.D.
Branch Chief
Division of Immunology and Hematology 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K214068

Device Name
Quantia IgE

Indications for Use *(Describe)*
Automated latex enhanced immunoassay for the quantitative in vitro determination of total immunoglobulin E (IgE) in human serum or plasma (EDTA, heparin, citrate) using the ARCHITECT c Systems. The measurement of total IgE is useful in the clinical diagnosis of IgE-mediated allergies, if used in conjunction with other clinical studies.

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

This 510(k) Summary is being submitted in accordance with the requirements of 21 CER 807.92 and the Safe Medical Device Act of 1990.

Submission Type	K214068 - Special 510(k)	
Submitter's Information	Biokit, S.A. Av. Can Montcau, 7 Lliçà d´Amunt, Barcelona 08186 Spain	
Contact Person	Àngels Roma Quality & Regulatory Affairs VP Phone: +34 (938) 609-000 Email: aroma@werfen.com	
Preparation Date	February 11th, 2023	
Device Trade Name	Quantia IgE (IgE, Antigen, Antiserum, Control)	
Regulatory Information	**Regulation Number**	21 CFR 866.5510
	Regulation Description	Immunoglobulins A, G, M, D and E immunological test system
	Classification	Class II
	Product Code	DGC
	Classification Panel	Immunology
Predicate Device	K050493	Quantia IgE
Device Description	The Quantia IgE reagent is a suspension of polystyrene latex particles of uniform size coated with mouse anti-human IgE. When a sample containing IgE is mixed with the latex reagent and the reaction buffer included in the kit, agglutination occurs. The degree of agglutination is directly proportional to the concentration of IgE in the sample and is determined by measuring the decrease of transmitted light caused by the aggregates. Methodology: Turbidimetric/Immunoturbidimetric.	

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Indications for Use / Intended Use	Automated latex enhanced immunoassay for the quantitative in vitro determination of total immunoglobulin E (IgE) in human serum or plasma (EDTA, heparin, citrate) using the ARCHITECT c Systems. The measurement of total IgE is useful in the clinical diagnosis of IgE-mediated allergies, if used in conjunction with other clinical studies.

Description of the Modification: The sample volume that is used by the assay is changed from 3.5 µL to 10.5 µL. Due to this modification, additional changes have been implemented in the assay parameters: Read times are changed from 26-27 to 24-25, the Sample Probe water SmartWash is added and the low-linearity is changed from 25.0 to 20.0 IU/mL. The correlation factor in the assay file is changed from 1.0000 to 1.0500. The changes to the Instruction for Use are detailed below.

Current Insert Summary and Principle (Excerpt)	**Updated Insert Summary and Principle (Excerpt) Revisions in *italic* and highlights**
PRINCIPLES OF THE PROCEDURE	**PRINCIPLES OF THE PROCEDURE**
---- (additional information is added)	*For additional information on system and assay technology, refer to the ARCHITECT System Operations Manual, Section 3.*
REAGENTS	**REAGENTS**
Reagent Kit	***Kit Contents***
---- (additional information is added)	*Volumes (mL) listed in the following table indicate the volume per vial.* *Test per vial set 69*
---- (additional information is added)	***Indications of Reagent Deterioration*** *Deterioration of the reagents may be indicated when a calibration error occurs or a control value is out of the specified range.* *Associated test results are invalid, and samples must be retested.* *Assay recalibration may be necessary.* *For troubleshooting information, refer to the ARCHITECT System Operations Manual, Section 10.*

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---- (additional information is added)	**INSTRUMENT PROCEDURE** *The Quantia IgE assay file must be installed on the ARCHITECT c System prior to performing the assay.* *For detailed information on assay file installation and viewing and editing assay parameters, refer to the ARCHITECT System Operations Manual, Section 2.* *For information on printing assay parameters, refer to the ARCHITECT System Operations Manual, Section 5.* *For a detailed description of system procedures, refer to the ARCHITECT System Operations Manual.*
SPECIMEN COLLECTION AND HANDLING **Suitable Specimens** • **Serum:** Use fresh serum collected by standard venipucture techniques. Ensure complete clot formation has taken place prior to centrifugation. Centrifuge according to tube manufacturer's instructions to ensure proper separation of serum blood cells. Gel separator tubes were not tested. Some specimens, especially those from patients receiving anticoagulant or thrombolytic therapy, may take longer to complete their clotting processes. Fibrin clots may subsequently form in these sera and the clots could cause erroneous test results. • **Plasma:** Use plasma collected by standard venipuncture techniques. The acceptable anticoagulanants are sodium EDTA, potassium EDTA, sodium heparin, lithium heparin, and citrate. Ensure centrifugation is adequate to remove platelets. Centrifuge according to tube manufacturer's instructions to ensure proper separation of plasma from bloods cells. Gel separator tubes were not tested. For total sample volume requirements, refer to the ASSAY PARAMETERS sections of this package insert and Section 5 of the ARCHITECT System Operations Manual.	**SPECIMEN COLLECTION AND PREPARATION FOR ANALYSIS** **Specimen Types** Specimen Types — Collection Tubes *Serum — Serum tubes *Plasma — Acceptable anticoagulants are: Sodium EDTA, Potassium EDTA, Sodium heparin, Lithium heparin, *Sodium* citrate * Gel separator tubes were not tested. *Other specimen types, collection tube types, and anticoagulants have not been verified with this assay.* *The instrument does not provide the capability to verify specimen types. It is the responsibility of the operator to verify that the correct specimen types are used in the assay.*
Sample Matrix (Serum vs. Plasma) Five sets of 52 paired samples were run. Sodium EDTA plasma, potassium EDTA plasma, sodium heparin plasma, lithium heparin plasma, and citrate	**Sample Matrix (Serum vs. Plasma)** *Forty* paired samples were run. Sodium EDTA plasma, potassium EDTA plasma, sodium heparin plasma, lithium heparin plasma, and

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plasma paired to serum samples were used. The linear regression statistics are shown below.

	Slope	Y - Intercept
Na-EDTA	0.968 (95% CI*: 0.963 to 0.973)	-1.553 (95% CI: -3.098 to -0.007)
K-EDTA	0.982 (95% CI: 0.976 to 0.989)	-1.878 (95% CI: -3.873 to 0.117)
Na-Heparin	0.978 (95% CI: 0.973 to 0.983)	-0.461 (95% CI: -1.983 to 1.060)
Li-Heparin	0.978 (95% CI: 0.973 to 0.983)	-1.272 (95% CI: -2.761 to 0.218)
Citrate	0.963 (95% CI: 0.955 to 0.972)	-2.226 (95% CI: -4.702 to 0.250)

*CI = Confidence Interval

Specimen Storage

Temperature	Maximum Storage	Bibliographic Reference
20 to 25°C	7 days	8
2 to 8°C	7 days	8, 9
-20°C	6 months	8

Guder et al.[8] suggest storage of frozen specimens at -20°C for no longer than the time interval cited above. However, limitations of laboratory equipment make it necessary in practice for clinical laboratories to establish a range around -20°C for specimen storage. This temperature range may be established from either the freezer manufacturer's specifications or your laboratory standard operating procedure(s) for specimen storage.

NOTE: Stored specimens must be inspected for particulates. If present, mix and centrifuge the specimen to remove particulates prior to testing.

---- (additional information is added)

sodium citrate plasma paired to serum samples were used. The linear regression statistics are shown below.

	Slope	**Y-Intercept**
Na-EDTA	0.98 (95% CI*: 0.97 to 1.00)	-1.08 (95% CI: -3.83 to 1.47)
K-EDTA	1.01 (95% CI: 0.99 to 1.03)	0.80 (95% CI: -0.77 to 2.19)
Na-Heparin	1.00 (95% CI: 0.98 to 1.01)	-1.22 (95% CI: -3.19 to 0.69)
Li-Heparin	0.98 (95% CI: 0.98 to 1.00)	1.23 (95% CI: -0.47 to 2.19)
Na-Citrate	0.97 (95% CI: 0.96 to 0.99)	-0.74 (95% CI: -2.39 to 0.91)

*CI = Confidence Interval

Specimen Storage

Specimen Type	**Temperature**	**Maximum Storage Time**	**Special Instructions**
Serum/Plasma	20 to 25°C	1 day	Specimens may be stored on the clot.
	2 to 8 °C	2 days	
	-20°C	12 days	Remove serum or plasma from the clot.

If testing will be delayed longer than the maximum 20 to 25°C or 2 to 8°C storage time, remove serum or plasma from the clot and store frozen (-20°C).
Each laboratory may establish a range around -20°C from either the freezer manufacturer's specifications or your laboratory standard operating procedure(s) for specimen storage.

NOTE: Stored specimens must be inspected for particulates. If present, mix and centrifuge the specimen to remove particulates prior to testing.

Specimen Shipping

Package and label specimens in compliance with applicable state, federal, and international regulations covering the transport of clinical specimens and infectious substances.
Do not exceed the storage limitations listed above.

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PROCEDURE **Materials Required but not Provided** ---- (additional information is added)	**PROCEDURE** **Materials Required but not Provided** *For information on materials required for operation of the instrument, refer to the ARCHITECT System Operations Manual, Section 1.* *For information on materials required for maintenance procedures, refer to the ARCHITECT System Operations Manual, Section 9.*
---- (additional information is added)	***Quality Control Guidance*** *Refer to "Basic QC Practices" by James O Westgard, Ph.D. for guidance on laboratory quality control practices.*
RESULTS Refer to Appendix C of the ARCHITECT System Operations Manual for information on results calculations.	**RESULTS** ***Calculation*** *For additional information on results calculations, refer to the ARCHITECT System Operations Manual, Appendix C.*
---- (additional information is added)	***Interpretation of Results*** *As with all analyte determinations, the IgE value should be used in conjunction with information available from clinical evaluation and other diagnostic procedures.*
---- (additional information is added)	***Flags*** *Some results may contain information in the Flags field. For a description of the flags that may appear in this field, refer to the ARCHITECT System Operations Manual, Section 5.*
---- (additional information is added)	***Reportable Interval*** *Based on representative data for the limit of quantitation (LoQ) and the limit of detection (LoD), the ranges over which results can be reported are provided below according to the definitions from CLSI EP34, 1st ed.*

	Units (IU/mL)
Analytical Measuring Interval (AMI)[a]	20.0 – 1000.0
Extended Measuring Interval (EMI)[b]	1000.0 – 10 000.0

[a] AMI: The AMI is determined by the range of values in IU/mL that demonstrated acceptable performance for linearity, imprecision, and bias.

	[b] *EMI: The EMI extends from the upper limit of quantitation (ULoQ) to the ULoQ x dilution factor. The value reflects a 1:10 dilution factor. NOTE: The default Low Linearity value of the assay file corresponds to the lower limit of the analytical measuring interval. Samples with an IgE value below the lower limit of the AMI are reported as < 20.0 IU/mL.*
LIMITATIONS OF THE PROCEDURE Refer to the SPECIMEN COLLECTION AND HANDLING and SPECIFIC PERFORMANCE CHARACTERISTICS sections of this package insert. No cross-reactivity studies have been conducted with heterophile antibodies. There is no prozone interference for undiluted samples containing up to 26,000.0 IU/mL of IgE. Sample concentrations higher than 26,000.0 IU/mL have not been tested. As the limit of quantification of Quantia IgE is 25.0 IU/mL, it is not recommended to use this test for children less than 12 months of age.	**LIMITATIONS OF THE PROCEDURE** Refer to the SPECIMEN COLLECTION AND *PREPARATION FOR ANALYSIS* and SPECIFIC PERFORMANCE CHARACTERISTICS sections of this package insert. No cross-reactivity studies have been conducted with heterophile antibodies. There is no prozone interference for undiluted samples containing up to *25 470.7* IU/mL of IgE. Sample concentrations higher than *25 470.7* IU/mL have not been tested. As the limit of quantification of Quantia IgE is *20.0* IU/mL, it is not recommended to use this test for children less than 12 months of age.
SPECIFIC PERFORMANCE CHARACTERISTICS ---- (additional information is added)	**SPECIFIC PERFORMANCE CHARACTERISTICS** *Representative performance data are provided in this section. Results obtained in individual laboratories may vary.*
Linearity Linearity was assessed according to Clinical and Laboratory Standards Institute (CLSI) protocol NCCLS EP6-A.[12] The reportable range of the Quantia IgE assay is 25.0 to 1000.0 IU/mL.	**Linearity** A study was performed based on guidance from CLSI EP06 2nd ed. Two high-analyte samples (human serum IgE at approximately 1040.1 and 1018.1 IU/mL) and 2 zero-analyte samples (IgE-depleted serum) were combined at different proportions to make 2 linearity panels that each consisted of samples with concentrations evenly distributed across the intended analytical measuring interval. The assay demonstrated acceptable linearity across the analytical measuring interval of 20.0 to 1000.0 IU/mL.
Limit of Quantification (LOQ) The LOQ of the Quantia IgE assay is 25.0 IU/mL. The LOQ was determined using dilutions of the 100 IU/mL level of the Quantia IgE Calibrator prepared in physiologic saline. The LOQ is defined as the	**Lower Limits of Measurement** *A study was performed based on guidance from CLSI EP17-A2. The limit of blank (LoB), limit of detection (LoD), and limit of quantitation (LoQ) values are summarized below. These*

lowest analyte concentration that can be measured with a within-run CV below 20% and the recovery is within ± 20% of expected value.

Limit of Detection (LOD)
The LOD of the Quantia IgE assay is 12.9 IU/mL, calculated by running 30 replicates of saline. LOD is defined as the mean concentration of an analyte-free sample + 2 SD, where SD is the within-run standard deviation.

Interfering Substances
…
Rheumatoid factor interference is less than 10% up to 138 IU/mL.
For a comprehensive review of interfering substances, refer to the publication by Young et al.[13]

representative data support the lower limit of the analytical measuring interval.

	IU/mL
LoB[a]	6.2
LoD[b]	11.6
LoQ[c]	20.0

[a] The LoB represents the 95th percentile from n ≥ 60 replicates of zero-analyte samples.
[b] The LoD represents the lowest concentration at which the analyte can be detected with 95% probability based on n ≥ 60 replicates of low-analyte level samples.
[c] The LoQ is defined as the lowest concentration at which a maximum allowable precision of 20 %CV and a maximum allowable bias of 20% were met and was determined from n ≥ 60 replicates of
low-analyte level samples and where the assay is linear.

Interfering Substances
…
Potentially Interfering Endogenous Substances

A study was performed based on guidance from CLSI EP07-A2. and CLSI EP37, 1st ed. Each substance was tested at 1 analyte level (approximately 90.0 IU/mL).

No Significant Interference (Interference within ± 5%)	
Potentially Interfering Substance	Interferent Level (mg/dL)
Bilirubin (conjugated)	40
Bilirubin (unconjugated)	40
Hemoglobin	1000
Lipemia (chyle)	2.4 AU/cm at 660 nm
Lipemia (triglyceride)	1500

Potentially Interfering Other Substances

A study was performed based on guidance from CLSI EP07-A2, CLSI EP07, 3rd ed. and CLSI EP37, 1st ed.

No Significant Interference (Interference within ± 10%)			
Potentially Interfering Substance	Interferent Concentration	IgE Target (IU/mL)	% Difference
HAMA	0.100 mg/dL	99.0	0.4
RF	138 IU/mL	90.0	1.3

Potentially Interfering Drugs

A study was performed based on guidance from CLSI EP07, 3rd ed. and CLSI EP37, 1st ed. Each

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Precision

The precision of the Quantia IgE assay is < 6% Total CV for Level II and a mixture of Levels I and II Control, and ≤ 15% for Level I Control (Quantia Ferritin/Myoglobin/IgE Control). Studies were performed using CLSI protocol NCCLS EP15-A.[14] Representative data are summarized below.

Control	Level I	Mixture of I and II	Level II
N	50	50	50
Mean (IU/mL)	46.3*	228.3	414.6
Within Run %CV	13.8	2.9	2.1
Total %CV	14.5	3.4	2.4

*Concentrations near the LOQ value produce slightly higher CVs.

substance was tested at 1 analyte level (approximately 99.0 IU/mL).

No Significant Interference (Interference within ± 10%)	
Potentially Interfering Drug	**Interferent Level (mg/dL)**
Acetaminophen	15.6
Acetylcysteine	15.0
Acetylsalicylic acid	3.00
Ampicillin	7.50
Cefoxitin	660
Cetirizine	0.435
Cyclosporine	0.180
Diphenhydramine	0.0774
Doxycycline	1.80
Fexofenadine	0.116
Heparin	330 units/dL
Ibuprofen	21.9
Levodopa	0.750
Methyldopa	2.25
Metronidazole	12.3
Mometasone	0.000045
Phenylbutazone	32.1
Prednisolone	0.120
Rifampicin	4.80
Salicylic Acid	2.86
Theophylline	6.00

Interferences from medication or endogenous substances may affect results.

Precision

Within-Laboratory Precision

A study was performed based on guidance from CLSI EP05-A3. Testing was conducted using 3 lots of the Quantia IgE reagent, 1 lot of the Quantia IgE Calibrator, 1 lot of the Quantia Ferritin/Myoglobin/IgE Control, and 1 instrument. Two controls, 1:1 mixture of control I and II, and 2 serum panels were tested in a minimum of 2 replicates, twice per day on 20 days.

Additional testing was conducted with 3 native serum pools using the same number of reagent, calibrator, and control lots and instruments utilized in the 20-day study. The 3 serum panels (Panel A, B, and C) were tested in a minimum of 2 replicates, twice per day on 12 days.

The performance from a representative combination is shown in the following table.

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Key to Symbols

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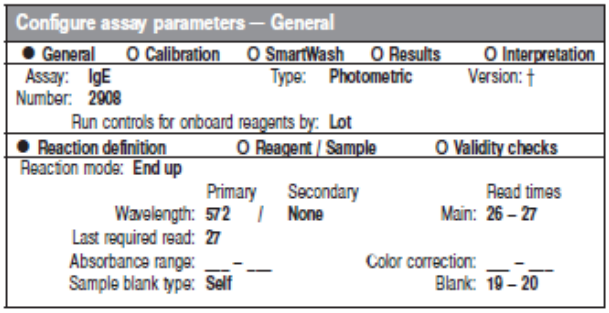
---- New symbol is added.

ARCHITECT *c*Systems Assays Parameters



Configure assay parameters — General

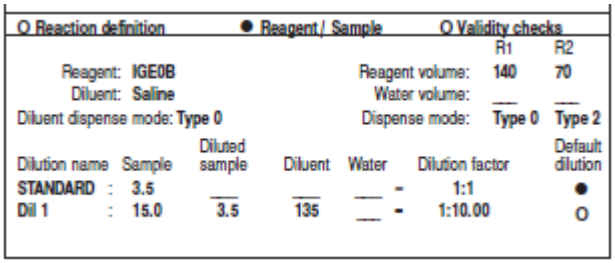
● General O Calibration O SmartWash O Results O Interpretation

Assay: IgE Type: Photometric Version: †
Number: 2908
Run controls for onboard reagents by: Lot

● Reaction definition O Reagent / Sample O Validity checks

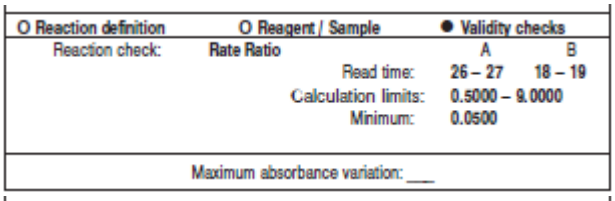
Reaction mode: End up

	Primary		Secondary		Read times
Wavelength:	572	/	None		Main: 26 – 27
Last required read:	27				
Absorbance range:	___ – ___				Color correction: ___ – ___
Sample blank type:	Self				Blank: 19 – 20



O Reaction definition ● Reagent / Sample O Validity checks

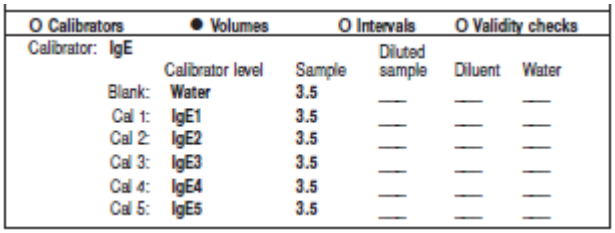
						R1	R2	
Reagent:	IGE0B				Reagent volume:	140	70	
Diluent:	Saline				Water volume:	___	___	
Diluent dispense mode:	Type 0				Dispense mode:	Type 0	Type 2	
Dilution name	Sample		Diluted sample	Diluent	Water	Dilution factor		Default dilution
STANDARD	: 3.5		___	___	___ -	1:1		●
Dil 1	: 15.0		3.5	135	___ -	1:10.00		O



O Reaction definition O Reagent / Sample ● Validity checks

		A	B
Reaction check:	Rate Ratio		
	Read time:	26 – 27	18 – 19
	Calculation limits:	0.5000 – 9.0000	
	Minimum:	0.0500	

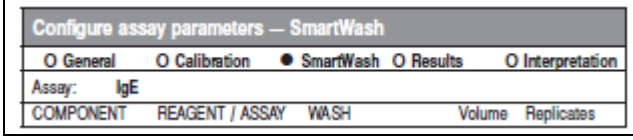
Maximum absorbance variation: ___



O Calibrators ● Volumes O Intervals O Validity checks

Calibrator: IgE

	Calibrator level	Sample	Diluted sample	Diluent	Water
Blank:	Water	3.5	___	___	___
Cal 1:	IgE1	3.5	___	___	___
Cal 2:	IgE2	3.5	___	___	___
Cal 3:	IgE3	3.5	___	___	___
Cal 4:	IgE4	3.5	___	___	___
Cal 5:	IgE5	3.5	___	___	___



Configure assay parameters — SmartWash

O General O Calibration ● SmartWash O Results O Interpretation

Assay: IgE

COMPONENT	REAGENT / ASSAY	WASH	Volume	Replicates

Sample	n	Mean (IU/mL)	Within-Run (Repeatability) SD	Within-Run (Repeatability) %CV	Within-Laboratory (Total)[a] SD	Within-Laboratory (Total)[a] %CV
Panel 50 IU/mL	80	53.4	2.1	3.9	2.1	3.9
Control I	80	69.6	1.9	2.7	2.0	2.8
1:1 Mix Control I and II	80	242.7	1.7	0.7	2.3	1.0
Control II	80	418.0	2.5	0.6	3.7	0.9
Panel 800 IU/mL	80	881.2	8.6	1.0	11.5	1.3
Panel A	48	26.9	0.9	3.3	1.3	4.9
Panel B	48	139.1	0.7	0.5	1.9	1.3
Panel C	48	461.6	1.7	0.4	5.4	1.2

[a] Includes within-run, between-run, and between-day variability.

Key to Symbols

…

Rx ONLY	For use by or on the order of a physician only (applicable to USA classification only).

---- (section deleted)

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Quantia IgE Serum/Plasma—Conventional and SI Units

Configure assay parameters — Results				
O General	O Calibration	O SmartWash	● Results	O Interpretation
Assay: IgE			Assay number: 2908	
Dilution default range:			Result units: IU/mL	
		Low-Linearity: 25.0		
		High-Linearity: 1000.0		
Gender and age specific ranges:**				
GENDER	AGE (UNITS)	NORMAL	EXTREME	

Configure result units	
Assay:	IgE
Version:	†
Result units:	IU/mL
Decimal places:	1 [Range 0 – 4]
Correlation factor:	1.0000
Intercept:	0.0000

Reason Submission Qualifies as Special 510(k)	This submission for the Quantia IgE assay meets the criteria for a Special 510(k) outlined in the FDA guidance "*The Special 510(k) Program: Guidance for Industry and Food and Drug Administration Staff"* (September 13, 2019) based on the following: • The proposed change is submitted by the manufacturer legally authorized to market the existing device. • Performance data is needed to evaluate the change. • There is a well-established method to evaluate the change. • The data can be reviewed in a summary or risk analysis format. In addition, the changes in this submission do not introduce: • Changes to indications for use or intended use • Changes to operating principle

Design Control Activities	The following studies were performed to verify performance of the modified device on ARCHITECT c8000 instrument: • Precision • Limit of blank (LoB) • Limit of detection (LoD) • Limit of quantitation (LoQ) • Linearity • Extended Measuring Interval/Autodilution • Prozone • Interferences • Tube type/Matrix comparison • Method Comparison • IgE International Standard recovery

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Comparison to Predicate Device (K050493)

The following is a description of the similarities and differences between the predicate device; Quantia IgE (K050493), and the subject device, modified Quantia IgE, to demonstrate substantial equivalence.

Similarities		
Item	**Predicate Device (K050493)**	**Subject Device**
Indications for Use / Intended Use	Quantia IgE is an automated latex enhanced immunoassay for the quantitative in vitro determination of immunoglobulin E (IgE) in human serum or plasma (EDTA, heparin, citrate) using the ARCHITECT c Systems. The measurement of IgE is useful in the clinical diagnosis of IgE-mediated allergies, if used in conjunction with other clinical studies.	Quantia IgE is an automated latex enhanced immunoassay for the quantitative in vitro determination of total immunoglobulin E (IgE) in human serum or plasma (EDTA, heparin, citrate) using the ARCHITECT c Systems. The measurement of total IgE is useful in the clinical diagnosis of IgE-mediated allergies, if used in conjunction with other clinical studies.
Measurand	IgE	Same
Type of Test	Quantitative	Same
Methodology	Latex-enhanced immuoturbidimetric assay	Same
Sample Type	Human serum or plasma (EDTA, heparin, citrate)	Same
Cut-off	N/A	Same
Kit Composition	The Quantia IgE kit consists of: • Latex Reagent: Suspension of polystyrene latex particles coated with anti-human IgE monoclonal antibody containing bovine serum albumin, glycine buffer, stabilizers and preservative. • Reaction Buffer: Glycine buffer containing bovine serum albumin, stabilizers and preservative.	Same

Differences		
Item	**Predicate Device (K050493)**	**Subject Device**
Linearity	25.0 – 1000.0 IU/mL	20.0 – 1000.0 IU/mL
Limit of Blank (LoB)	Not defined.	6.2 IU/mL
Limit of Detection (LoD)	12.9 IU/mL	11.6 IU/mL
Limit of Quantitation (LoQ)	25.0 IU/mL	20.0 IU/mL

The conclusions drawn from the nonclinical and clinical tests demonstrate that the device is as safe, as effective, and performs as well as the legally marketed device (K050493 Quantia IgE) identified at the beginning of this section.