



September 30, 2026

Revvity, Inc.
Lisa Vershave
Regulatory Affairs Manager
77 4th Ave.
Waltham, Massachusetts 02451

Re: K262893

Trade/Device Name: Eonis™ SMA kit
Regulation Number: 21 CFR 866.5980
Regulation Name: Spinal Muscular Atrophy Newborn Screening Test System
Regulatory Class: Class II
Product Code: QUE
Dated: August 17, 2026
Received: August 17, 2026

Dear Lisa Vershave:

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.

Before making any change significantly affecting the safety or effectiveness of the device, you must submit a new premarket notification in accordance with 21 CFR 807.81. 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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

PAULA V. CAPOSINO -S

Paula Caposino, Ph.D.
Deputy Director
Division of Chemistry and
Toxicology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K262893

Device Name

Eonis™ SMA kit

Indications for Use (Describe)

The Eonis™ SMA kit is intended for the qualitative detection of the SMN1 gene exon 7 as an aid in screening newborns for Spinal Muscular Atrophy (SMA). The test is intended for DNA from blood specimens dried on a filter paper and for use on the Eonis Q or QuantStudio™ Dx Real-Time PCR instrument.

This test is only intended for use for screening of SMA that bear the homozygous deletion of SMN1 exon 7.

This test is not intended for use as a diagnostic test and a positive screening result should be followed by confirmatory 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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8.03.01_510(k) Summary

This summary of safety and effectiveness information is supplied in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned number is: K262893

Date: September 30, 2026

Submitted by:	Revvity, Inc. 77 4th Avenue Waltham, MA US 02451
Contact Person:	Lisa Vershave Email: americas.regulatory@revvity.com
Trade Name:	Eonis™ SMA kit
Common Name:	Eonis™ SMA kit
Regulation:	21 CFR 866.5980
Classification Name:	Spinal Muscular Atrophy Newborn Screening Test System
Classification:	Immunology
Product Code:	QUE
Predicate Device:	Eonis SCID-SMA kit (DEN200044)

Intended Use:

The Eonis™ SMA kit is intended for the qualitative detection of the SMN1 gene exon 7 as an aid in screening newborns for Spinal Muscular Atrophy (SMA). The test is intended for DNA from blood specimens dried on filter paper and for use on the Eonis Q or QuantStudio™ Dx Real-Time PCR instrument.

This test is only intended for use for screening of SMA that bear the homozygous deletion of SMN1 exon 7.

This test is not intended for use as a diagnostic test and a positive screening result should be followed by confirmatory testing.

Device Description:

The Eonis™ SMA kit contains reagents to detect exon 7 in the SMN1 gene that was submitted and reviewed in DEN200044.

The newborn screening workflow for the Eonis™ SMA Kit includes:

- Two liquid handling platforms (one for DNA extraction and one for PCR master mix setup)
- Eonis Q Instrument or QuantStudio™ Dx Real-Time PCR instrument
- Eonis EASI software (used with Eonis Q instrument) or the Eonis Analysis Software (used with the QuantStudio™ Dx Real-Time PCR instrument)

Each Eonis™ SMA kit contains reagents for up to 384 reactions or 1152 reactions including kit controls. The kit contents are listed in Table 1. Materials required but not provided in the kit include the Eonis DNA Extraction Kit, Eonis EASI software or Eonis Analysis Software, and consumables.

Table 1. Eonis™ SMA kit Content

Component	Quantity
SCID-SMA Kit Controls	2 filter paper cassettes containing 4 sets of dried blood spots for 384 reaction kit 4 filter paper cassettes containing 8 sets of dried blood spots for 1152 reaction kit
C1 Analyte-negative (SMN1) control	
C2 Normal SMN1 control	
C3 Normal SMN1 control	
PCR Reagent 1	1 vial, 2.7 mL for 384 reaction kit 3 vials, 2.7 mL each for 1152 reaction kit
PCR Reagent 2	1 vial, 2.7 mL for 384 reaction kit 3 vials, 2.7 mL each for 1152 reaction kit
Lot-specific quality control certificate	1 pc

Principle of Operation

The Eonis™ SMA kit is a multiplex real-time PCR–based assay that utilizes target sequence–specific primers and TaqMan™ probes to simultaneously amplify and detect SMN1 exon 7, and RPP30, in DNA extracted from newborn dried blood spots (DBS) using the Eonis DNA Extraction Kit. Targets are amplified within a single PCR reaction.

Each TaqMan™ probe incorporates a unique fluorescent dye at the 5' end, enabling concurrent detection of all targets when present. During PCR amplification, the probes are cleaved, releasing fluorophores whose emitted signals are measured in real-time by the Eonis Q or QuantStudio™ Dx Real-Time PCR instruments. The instruments convert fluorescence intensity into comparative quantitative results expressed as cycle threshold (Ct) values.

This multiplex real-time PCR approach enables simultaneous detection of the specified targets to support screening for spinal muscular atrophy (SMA) using a single DBS-derived DNA sample.

The interpretation of results based on Ct is shown in Table 2.

Table 2. SMN1 Result Interpretation Matrix

RPP30 Ct values		SMN1 Ct values	Result interpretation for SMN1
Ct < 15.0	Values not considered when RPP30 Ct < 15.0		Invalid*
15.0 ≤ Ct ≤ 32.00	AND	Ct < 15.0	Invalid*
	AND	15.0 ≤ Ct ≤ 31.24	Presumptive normal
	AND	Ct > 31.24 or no Ct	Presumptive positive*
Ct > 32.00 or no Ct	Values not considered when RPP30 Ct > 32.00 or no Ct		Invalid*

*Samples with invalid results should be repeated in singlicate, samples with presumptive positive results should be repeat tested in duplicate. If one of the duplicate samples is positive, the result is presumptive positive.

Substantial Equivalence:

The predicate device is the Eonis SCID-SMA Kit cleared under DEN200044. The proposed device, the Eonis™ SMA kit, retains the same SMA assay design, intended use, specimen type, analytes, test methodology, and result interpretation as the predicate device. The assay utilizes multiplex real-time PCR amplification and detection of SMN1 exon 7 and RPP30 from DNA extracted from newborn dried blood spot specimens.

The primary modification is the addition of the Eonis Q instrument and Eonis EASI software as an alternative testing platform to the QuantStudio™ Dx Real-Time PCR Instrument and associated analysis software. The Eonis™ SMA kit may be used with either platform.

Performance testing demonstrated that the addition of the Eonis Q instrument and Eonis EASI software does not affect the performance of the Eonis™ SMA kit. The differences between the proposed device and the predicate device do not raise new questions of safety or effectiveness. Therefore, the proposed device is substantially equivalent to the predicate device.

Table 3. Substantial Equivalency

Parameter	Predicate: DEN200044	New Device (changes in bold font)
Device Trade Name	Eonis SCID-SMA kit	Eonis™ SMA kit

Parameter	Predicate: DEN200044	New Device (changes in bold font)
Intended Use / Indications for Use	The Eonis SCID-SMA kit is intended for the qualitative detection of the SMN1 gene exon 7 as an aid in screening newborns for Spinal Muscular Atrophy (SMA). The test is intended for DNA from blood specimens dried on filter paper and for use on the QuantStudio Dx Real-Time PCR instrument. This test is only intended for use for screening of SMA that bear the homozygous deletion of SMN1 exon 7. This test is not intended for use as a diagnostic test and a positive screening result should be followed by confirmatory testing.	The Eonis™ SMA kit is intended for the qualitative detection of the SMN1 gene exon 7 as an aid in screening newborns for Spinal Muscular Atrophy (SMA). The test is intended for DNA from blood specimens dried on filter paper and for use on the Eonis Q or QuantStudio Dx Real-Time PCR instrument. This test is only intended for use for screening of SMA that bear the homozygous deletion of SMN1 exon 7. This test is not intended for use as a diagnostic test and a positive screening result should be followed by confirmatory testing.
Disorders Screened	SMA	Same.
Analytes Measured	SMN1 exon 7 and RPP30 (internal control).	Same.
Test Principle	The assay amplifies and detects SMN1 exon 7 and RPP30 simultaneously in the DNA extracted from whole blood collected from a heel prick with direct application onto the filter paper (also called Dried Blood Spot, DBS) in a multiplex PCR reaction using target-specific primers and TaqMan probes.	Same.
Sample Requirements	Dried blood spot.	Same.
Calibrators/Standards	Calibration is based on internal reference (RPP30) in each well and manufacturer calibration for each kit lot.	Same.
Controls	C1 Analyte-negative (SMN1) control, C2 Normal SMN1 control, C3 Normal SMN1 control.	Same.
Test Methodology	Semi-quantitative, multiplex real-time fluorescent-based polymerase chain reaction (PCR) based nucleic acid amplification and detection.	Same.

Parameter	Predicate: DEN200044	New Device (changes in bold font)
Instruments / Software	QuantStudio Dx-Real Time PCR Instrument and Eonis Analysis Software.	QuantStudio Dx-Real Time PCR Instrument and Eonis Analysis Software and Eonis Q instrument and Eonis EASI software.
Result Types/Calculations	Produce Ct values.	Same.
Interpretation of results	SMN1 is qualitative.	Same.

Summary of Studies:

Screening Performance

The screening performance of the Eonis™ SMA kit on Eonis Q and QuantStudio™ Dx instruments was compared in a clinical study at a US newborn screening laboratory. Study population included 2079 routine newborn samples enriched with 20 SMA newborn DBS specimens and 2 non-newborn SMA specimens (with SMN2 copy number 4) that were archived and confirmed positive. The samples were tested according to the testing algorithm described in tables 4.

The SMN1 Ct cut-off is pre-set at 31.24 with both Eonis Q and QuantStudio™ Dx. The screening performance results including the confirmed positive specimens, are present in Table 4.

Table 4. Screening Performance of Eonis™ SMA kit with Eonis Q and QuantStudio™ Dx.

SMN1		QuantStudio™ Dx		Total (%)
		Presumptive positive (%)	Presumptive normal (%)	
Eonis Q	Presumptive positive (%)	22*	0	22
	Presumptive normal (%)	0	2079	2079
	Total (%)	22	2079	2101

*Includes 22 SMA confirmed positive samples

Analytical Performance

Reproducibility and Precision

Two studies were performed to determine the reproducibility and precision of the Eonis™ SMA kit using a panel of dried blood spots at different SMN1 levels. Hematocrits were adjusted between 40%-55% with normal RPP30 levels.

All 104 plates from both studies had results of the Kit Controls within the acceptance limits. The data validity check for 3757 wells resulted in no exclusions from the analysis (sample invalid rate is 0%).

Site-to-Site Reproducibility

The objective of this study was to characterize the within-laboratory precision and reproducibility of the Eonis Q across 3 study sites. Setup included 1 reagent kit lot, 2 external newborn screening laboratories and 1 internal site. In each laboratory, 2 operators performed 5 runs each during 5 operating days. Each run consisted of 1 plate with 5 replicates per sample. Total number of measurements was 150 per sample (50 replicates per sample in each laboratory).

For qualitative analyte, SMN1, the precision is presented as the percent agreement of qualitative results interpreted with respect to cut-off 31.24 Ct for each sample in Table 5, for SMN1 Ct values in Table 6, and RPP30 Ct values in Table 7 for Eonis Q.

Table 5. SMN1 reproducibility data.

Sample	N	Proportion Below Cut-off (%) (with 95% CI)	Proportion Above Cut-off (%) (with 95% CI)
1	150	100% (97.6% - 100%)	0
2	150	100% (97.6% - 100%)	0
3	150	100% (97.6% - 100%)	0
4	150	100% (97.6% - 100%)	0
5	150	100% (97.6% - 100%)	0
6	150	100% (97.6% - 100%)	0
7	150	100% (97.6% - 100%)	0
8	150	100% (97.6% - 100%)	0
9	150	100% (97.6% - 100%)	0
10	150	100% (97.6% - 100%)	0
11	150	0	100% (97.6% - 100%)
12	150	100% (97.6% - 100%)	0
13	150	100% (97.6% - 100%)	0
14	150	100% (97.6% - 100%)	0
15	150	100% (97.6% - 100%)	0

Table 6. SMN1 reproducibility analysis on Ct values for samples. All replicate results for Sample 11 (SMA positive) are “No Ct” and thus not included in the table.

Sample	N	CT Mean	Within Run		Between Run		Between Operator		Between Site		Total	
			SD	CV%	SD	CV%	SD	CV%	SD	CV%	SD	CV%
1	150	24.6	0.38	1.5	0.00	0.0	0.00	0.0	0.14	0.6	0.40	1.6
2	150	24.5	0.46	1.9	0.16	0.6	0.00	0.0	0.06	0.2	0.49	2.0
3	150	24.5	0.58	2.4	0.04	0.2	0.00	0.0	0.26	1.1	0.64	2.6
4	150	25.8	0.37	1.4	0.00	0.0	0.00	0.0	0.12	0.5	0.39	1.5
5	150	26.1	0.34	1.3	0.11	0.4	0.02	0.1	0.18	0.7	0.41	1.6
6	150	25.0	0.30	1.2	0.08	0.3	0.00	0.0	0.19	0.7	0.36	1.4
7	150	26.1	0.48	1.8	0.06	0.2	0.00	0.0	0.15	0.6	0.50	1.9

Sample	N	CT Mean	Within Run		Between Run		Between Operator		Between Site		Total	
			SD	CV%	SD	CV%	SD	CV%	SD	CV%	SD	CV%
8	150	26.4	0.33	1.2	0.00	0.0	0.02	0.1	0.15	0.6	0.36	1.4
9	150	24.9	0.35	1.4	0.07	0.3	0.00	0.0	0.10	0.4	0.37	1.5
10	150	27.8	0.43	1.5	0.13	0.5	0.00	0.0	0.16	0.6	0.48	1.7
12	150	25.9	0.36	1.4	0.10	0.4	0.08	0.3	0.14	0.6	0.41	1.6
13	150	24.9	0.39	1.6	0.08	0.3	0.06	0.2	0.09	0.3	0.41	1.7
14	150	26.9	0.36	1.3	0.13	0.5	0.00	0.0	0.09	0.3	0.39	1.4
15	150	24.8	0.34	1.4	0.10	0.4	0.00	0.0	0.16	0.7	0.39	1.6

Table 7. RPP30 reproducibility analysis on Ct values.

Sample	N	CT Mean	Within Run		Between Run		Between Operator		Between Site		Total	
			SD	CV%	SD	CV%	SD	CV%	SD	CV%	SD	CV%
1	150	25.7	0.44	1.7	0.17	0.7	0.00	0.0	0.07	0.3	0.48	1.9
2	150	25.7	0.53	2.1	0.15	0.6	0.00	0.0	0.04	0.2	0.55	2.2
3	150	25.7	0.62	2.4	0.20	0.8	0.00	0.0	0.23	0.9	0.69	2.7
4	150	27.0	0.47	1.8	0.21	0.8	0.00	0.0	0.08	0.3	0.53	1.9
5	150	27.3	0.47	1.7	0.30	1.1	0.00	0.0	0.20	0.7	0.59	2.2
6	150	26.4	0.42	1.6	0.25	0.9	0.00	0.0	0.13	0.5	0.51	1.9
7	150	27.3	0.61	2.3	0.18	0.6	0.00	0.0	0.11	0.4	0.65	2.4
8	150	27.7	0.42	1.5	0.29	1.1	0.00	0.0	0.13	0.5	0.53	1.9
9	150	25.3	0.46	1.8	0.19	0.7	0.00	0.0	0.13	0.5	0.52	2.0
10	150	28.5	0.73	2.6	0.00	0.0	0.00	0.0	0.35	1.2	0.81	2.8
11	150	24.1	0.40	1.7	0.15	0.6	0.00	0.0	0.17	0.7	0.46	1.9
12	150	27.1	0.44	1.6	0.27	1.0	0.00	0.0	0.09	0.3	0.53	1.9
13	150	26.3	0.52	2.0	0.00	0.0	0.00	0.0	0.03	0.1	0.52	2.0
14	150	28.2	0.43	1.5	0.21	0.7	0.00	0.0	0.15	0.6	0.50	1.8
15	150	25.4	0.47	1.9	0.10	0.4	0.00	0.0	0.17	0.7	0.52	2.0

Lot-to-lot Reproducibility

This study was performed internally (single site) using 3 sets of Eonis Q at least 2 operators and 3 kit lots. The samples 1-14 were tested over a minimum of 23 calendar days with 2 replicates per sample per plate in a total of 72 runs for Eonis Q with a randomized plate map. Total number of measurements were 108 per sample.

For qualitative analyte, SMN1, the precision is presented as the percent agreement of qualitative results interpreted with respect to cut-off 31.24 Ct for each sample in Table 8, for SMN1 Ct values in Table 19 and for RPP30 Ct values in Table 10 for Eonis Q.

Table 8. SMN1 precision data.

Sample	N	N (below cut-off)	Proportion Normal (%) (with 95% CI)	N (above cut-off)	Proportion Positive (%) (with 95% CI)
1	107	107	100 (96.6 %-100.0 %)	0	0

Sample	N	N (below cut-off)	Proportion Normal (%) (with 95% CI)	N (above cut-off)	Proportion Positive (%) (with 95% CI)
2	108	108	100 (96.6 %-100.0 %)	0	0
3	108	108	100 (96.6 %-100.0 %)	0	0
4	108	108	100 (96.6 %-100.0 %)	0	0
5	107	107	100 (96.6 %-100.0 %)	0	0
6	108	108	100 (96.6 %-100.0 %)	0	0
7	108	108	100 (96.6 %-100.0 %)	0	0
8	108	108	100 (96.6 %-100.0 %)	0	0
9	108	108	100 (96.6 %-100.0 %)	0	0
10	108	108	100 (96.6 %-100.0 %)	0	0
11	106	0	0	106	100 (96.6 %-100.0 %)
12	108	108	100 (96.6 %-100.0 %)	0	0
13	108	108	100 (96.6 %-100.0 %)	0	0
14	107	107	100 (96.6 %-100.0 %)	0	0

Table 9. SMN1 precision analysis on Ct values for samples. All replicate results for Sample 11 are “No Ct” and thus not included in the table.

Sample	N	Mean Ct	Repeatability		Between Run		Between System		Within Lot		Between Lot		Total	
			SD	CV %	SD	CV %	SD	CV %	SD	CV %	SD	CV %	SD	CV %
1	107	24.4	0.42	1.7	0.13	0.5	0.15	0.6	0.47	1.9	0.17	0.7	0.50	2.0
3	108	24.4	0.50	2.1	0.27	1.1	0.12	0.5	0.59	2.4	0.18	0.7	0.61	2.5
2	108	24.5	0.33	1.4	0.14	0.6	0.17	0.7	0.39	1.6	0.10	0.4	0.41	1.7
13	108	24.8	0.30	1.2	0.00	0.0	0.16	0.6	0.34	1.4	0.08	0.3	0.35	1.4
9	108	24.8	0.29	1.2	0.15	0.6	0.00	0.0	0.33	1.3	0.11	0.5	0.35	1.4
6	108	24.8	0.26	1.0	0.23	0.9	0.10	0.4	0.36	1.4	0.09	0.4	0.37	1.5
4	108	25.6	0.28	1.1	0.19	0.7	0.14	0.5	0.37	1.4	0.09	0.3	0.38	1.5
12	108	25.8	0.33	1.3	0.14	0.5	0.07	0.3	0.37	1.4	0.07	0.3	0.37	1.4
7	108	25.9	0.37	1.4	0.22	0.8	0.00	0.0	0.43	1.7	0.15	0.6	0.45	1.8
5	107	26.0	0.32	1.2	0.12	0.5	0.14	0.5	0.37	1.4	0.06	0.2	0.38	1.4
8	108	26.4	0.31	1.2	0.13	0.5	0.00	0.0	0.34	1.3	0.16	0.6	0.37	1.4
14	107	26.8	0.34	1.3	0.12	0.4	0.19	0.7	0.41	1.5	0.11	0.4	0.42	1.6
10	108	27.8	0.38	1.4	0.19	0.7	0.13	0.5	0.44	1.6	0.27	1.0	0.52	1.9

Table 10. RPP30 precision analysis on Ct values.

Sample	N	Mean Ct	Repeatability		Between Run		Between System		Within Lot		Between Lot		Total	
			SD	CV %	SD	CV %	SD	CV %	SD	CV %	SD	CV %	SD	CV %
11	106	24.1	0.33	1.4	0.17	0.7	0.07	0.3	0.38	1.6	0.02	0.1	0.38	1.6
9	108	25.3	0.41	1.6	0.00	0.0	0.00	0.0	0.41	1.6	0.10	0.4	0.42	1.7
3	108	25.7	0.60	2.4	0.14	0.6	0.00	0.0	0.62	2.4	0.09	0.4	0.63	2.4
1	107	25.7	0.40	1.6	0.21	0.8	0.09	0.4	0.46	1.8	0.09	0.4	0.47	1.8

Sample	N	Mean Ct	Repeatability		Between Run		Between System		Within Lot		Between Lot		Total	
			SD	CV %	SD	CV %	SD	CV %	SD	CV %	SD	CV %	SD	CV %
2	108	25.7	0.45	1.7	0.00	0.0	0.07	0.3	0.46	1.8	0.08	0.3	0.46	1.8
13	108	26.2	0.40	1.5	0.19	0.7	0.00	0.0	0.44	1.7	0.04	0.2	0.45	1.7
6	108	26.3	0.39	1.5	0.07	0.3	0.11	0.4	0.42	1.6	0.03	0.1	0.42	1.6
4	108	26.9	0.44	1.6	0.18	0.7	0.09	0.3	0.48	1.8	0.01	0.0	0.48	1.8
12	108	27.2	0.47	1.7	0.14	0.5	0.12	0.4	0.51	1.9	0.09	0.3	0.51	1.9
7	108	27.2	0.43	1.6	0.19	0.7	0.08	0.3	0.47	1.7	0.02	0.1	0.47	1.7
5	107	27.3	0.42	1.5	0.11	0.4	0.15	0.6	0.46	1.7	0.09	0.3	0.47	1.7
8	108	27.8	0.43	1.6	0.05	0.2	0.17	0.6	0.47	1.7	0.05	0.2	0.47	1.7
14	107	28.1	0.43	1.5	0.00	0.0	0.16	0.6	0.46	1.6	0.09	0.3	0.46	1.6
10	108	28.4	0.61	2.2	0.18	0.6	0.05	0.2	0.64	2.3	0.08	0.3	0.65	2.3

Limit of Blank (LoB)

The Limit of Blank (LoB) was determined in accordance with CLSI document EP17-A2. The data for LoB was analyzed using “Assign LoB = Zero and Confirm” approach. The LoB of the Eonis Q is zero for SMN1 and RPP30.