November 5, 2018

Roche Diagnostics Operations (RDO)
Lindsay Jones
Regulatory Affairs Consultant
9115 Hague Road
Indianapolis, Indiana 46250

Re: K182095
Trade/Device Name: Tina-quant Transferrin ver.2 (urine application)
Regulation Number: 21 CFR 866.5880
Regulation Name: Transferrin immunological test system
Regulatory Class: Class II
Product Code: DDG
Dated: August 1, 2018
Received: August 3, 2018

Dear Lindsay Jones:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Leonthena R. Carrington -S

Lea Carrington
Director
Division of Immunology
and Hematology Devices
Office of In Vitro Diagnostics
and Radiological Health
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K182095

Device Name
Tina-quant Transferrin ver.2 (urine application)

Indications for Use *(Describe)*
Tina-quant Transferrin ver.2 (urine application) assay is an in vitro test for the quantitative determination of transferrin in human urine on Roche/Hitachi cobas c systems.

A transferrin immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the transferrin (an iron-binding and transporting serum protein) in urine. Measurement of transferrin levels aids in the diagnosis of malnutrition, acute inflammation, infection, and red blood cell disorders, such as iron deficiency anemia.

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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Tina-quant Transferrin ver.2 (urine application)
510(k) Summary (K182095)

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

In accordance with 21 CFR 807.87, Roche Diagnostics hereby submits official notification as required by Section 510(k) of the Federal Food, Drug and Cosmetics Act of our intention to market the device described in this Premarket Notification 510(k).

The purpose of this Traditional 510(k) Premarket Notification is to obtain FDA review and clearance for the Tina-quant Transferrin ver.2 (urine application).

Submitter Name	Roche Diagnostics Operations (RDO)
Address	9115 Hague Road Indianapolis, IN 46250, USA
Contact	Lindsay Jones Phone: (317) 521-3544 FAX: (317) 521-2324 Email: lindsay.jones.lj1@roche.com
Date Prepared	November 1, 2018
Proprietary Name	Tina-quant Transferrin ver.2 (urine application)
Common Name	Transferrin
Classification Name	Transferrin immunological test system, Class II
Product Codes, Regulation Numbers	DDG, 21 CFR § 866.5880
Predicate Devices	N Antisera to Human Transferrin (K053075)
Establishment Registration	For the Tina-quant Transferrin ver.2 (urine application), the establishment registration number for Roche Diagnostics GmbH in Mannheim, Germany is 9610126.

1. DEVICE DESCRIPTION

The Tina-quant Transferrin ver.2 (urine application) assay is a two reagent assay for the in vitro quantitative determination of transferrin in human urine on automated clinical chemistry analyzers. It is an immunoturbidimetric assay in which human transferrin forms a precipitate with a specific antiserum which is determined turbidimetrically.

Engineering drawings, schematics, and figures are not pertinent to describe the device, as the device is a reagent.

2. INDICATIONS FOR USE

Tina-quant Transferrin ver.2 (urine application) assay is an in vitro test for the quantitative determination of transferrin in human urine on Roche/Hitachi **cobas c** systems.

A transferrin immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the transferrin (an iron-binding and transporting serum protein) in urine. Measurement of transferrin levels aids in the diagnosis of malnutrition, acute inflammation, infection, and red blood cell disorders, such as iron deficiency anemia.

3. TECHNOLOGICAL CHARACTERISTICS

The Roche transferrin assay is based on the immunological agglutination principle. Human transferrin forms a precipitate with a specific antiserum which is determined turbidimetrically.

The following table compares the Tina-quant Transferrin ver.2 (urine application) with its predicate device, N Antisera to Human Transferrin (K053075). See Table 1 below.

Table 1: Assay Comparison

Feature	Predicate Device N Antisera to Human Transferrin (K053075)	Candidate Device Tina-quant Transferrin ver.2 (urine application)
Intended Use	In vitro diagnostic reagents for the quantitative determination of transferrin and haptoglobin in human serum, heparinized and EDTA plasma, as well as transferrin in human urine by means of immunonephelometry on the BN II and BN™ ProSpec System.	In vitro test for the quantitative determination of transferrin in human urine on Roche/Hitachi **cobas c** systems.
Test Principle	Proteins contained in human body fluids form immune complexes in an immunochemical reaction with specific antibodies. These complexes scatter a beam of light passed through the sample. The intensity of the scattered light is proportional to the concentration of the relevant protein in the sample. The result is evaluated by comparison with a standard of known concentration.	Human transferrin forms a precipitate with a specific antiserum which is determined turbidimetrically.
Instrument	BN II/BN ProSpec System	**cobas c** 501
Reagent Composition	N Antisera are liquid animal sera and are produced by immunization of rabbits with highly purified human transferrin. The concentration of active antibodies is < 4.2 g/L to human transferrin. Preservative Sodium azide <1 g/L	R1: Phosphate buffer: 55 mmol/L, pH 7.2; NaCl: 25 mmol/L; polyethylene glycol: 5 %; preservative R2: Anti-human transferrin antibodies (rabbit): dependent on titer; NaCl: 100 mmol/L; preservative
Sample Type/Matrix	Serum, heparinized and EDTA plasma, urine	Urine
Calibrator	N Protein Standard SL	S1: H_2O S2 – S6: Calibrator for automated systems (C.f.a.s.) Proteins (K133330)
Calibration Interval	The reference curves can be used for as long as controls with corresponding method-depending target values, e.g. N/T Protein Controls SL/L, M and H or N/T Protein Control LC, are reproduced within their respective range. If a different lot of antiserum is used, a new reference curved must be generated.	Full calibration: • after reagent lot change • as required following quality control procedures

Feature	Predicate Device N Antisera to Human Transferrin (K053075)	Candidate Device Tina-quant Transferrin ver.2 (urine application)
Controls	Serum/plasma: N/T Protein Controls SL/L, M, and H Urine: N/T Protein Control LC	PreciControl ClinChem Multi 1 & PreciControl ClinChem Multi 2 (K133330) Precinorm Protein & Precipath Protein (K133330)
Reagent Shelf-Life Stability	Stability at 2 – 8 °C: See expiry date on label. Stability once opened: 4 weeks if stored at 2 – 8 °C securely capped immediately after each use and contamination (e.g., by microorganisms) is precluded. During storage, N Antisera can develop precipitates or turbidity which are not caused by microbial contamination and which do not affect their activity. In such cases, the antiserum should be filtered prior to use. Disposable filters with a pore size of 0.45 µm are suitable for this purpose. Do not freeze.	Shelf life at 2 – 8 °C: See expiration date on cobas c pack label.
Reagent On-Board Stability	A minimum of 5 days at 8 hours per day for 5 mL vials, and 3 days at 8 hours per day for 2 mL vials or a comparable period of time.	On-board in use and refrigerated on the analyzer: 8 weeks
Measuring Range	Serum/plasma: 35.0 to 560 mg/dL Urine: 0.22 to 3.5 mg/dL	0.22 to 3.5 mg/dL
Reference Range	Reference interval for urinary transferrin: the concentration of transferrin in the urine of healthy individuals is below the detection limit of this method. Nevertheless, each laboratory should determine its own reference intervals since values may vary depending on the individual population studied. Siemens has not established reference ranges for children.	≤ 1.9 mg/L* (0.19 mg/dL) * The concentration of transferrin in urine of healthy individuals is below the detection limit of this method. Each laboratory should investigate the transferability of the expected values to its own patient population and if necessary determine its own reference ranges.

Feature	Predicate Device N Antisera to Human Transferrin (K053075)	Candidate Device Tina-quant Transferrin ver.2 (urine application)
Sample Stability	Suitable samples are human serum, heparinized or EDTA plasma as fresh as possible (stored no more than 7 days at 2 – 8 ºC), or stored frozen and fresh human urine. Serum and plasma samples can be stored at below – 20 ºC for up to 3 months if they are frozen within 24 hours after collection and if repeated freeze thaw cycles are avoided. Serum samples must be completely coagulated and, after centrifugation, must not contain any particles or traces of fibrin. Lipemic samples or frozen samples that are turbid after thawing must be clarified by centrifugation (10 minutes at approximately 15,000 x g) prior to testing. Random and timed urine collections are suitable specimens for testing transferrin in urine. Urine samples must not be frozen. Each urine samples must be centrifuged prior to testing.	4 days at 15 – 25 ºC 7 days at 2 – 8 ºC Freezing and thawing is not allowed

4. NON-CLINICAL PERFORMANCE EVALUATION

The following performance data were provided in support of the substantial equivalence determination:

Precision according to CLSI EP05-A3

Detection Limit: LoB, LoD, LoQ according to CLSI EP17-A2

Linearity according to CLSI EP06-A

Endogenous Interferences

Exogenous Interferences – Drugs

Method Comparison to Predicate

All performance specifications were met.

4.1. Precision

4.1.1. Repeatability and Intermediate Precision

Precision experiments were performed in accordance with CLSI Guideline EP05-A3. The testing was run for 21 days, including 1 run per day with 2 parts. Ten dummy samples were included in each part to simulate routine testing in the laboratory. Additionally, 10 dummy samples were included in-between both parts to divide the run into distinct parts. Five human urine sample pools and 2 control samples were tested on one **cobas c** 501, using 3 lots of reagent. Each sample was tested using 2 aliquots in singlicate per part. Mean, Repeatability (within-run precision) and Intermediate precision (within-lab precision) % CV and SD values were calculated.

4.1.2. Results and Conclusions

Table 2: Repeatability Summary

Specimen	Mean (mg/dL)	SD (mg/dL)	CV (%)
PreciControl ClinChem Multi 1	1.98	0.0140	**0.7**
PreciControl ClinChem Multi 2	3.05	0.0242	**0.8**
Human Urine 1	0.435	0.00979	2.3
Human Urine 2	0.737	0.00920	1.2
Human Urine 3	1.27	0.0107	0.8
Human Urine 4	2.52	0.0184	0.7
Human Urine 5	3.30	0.0252	0.8

Table 3: Intermediate Precision Summary

Specimen	Mean (mg/dL)	SD (mg/dL)	CV (%)
PreciControl ClinChem Multi 1	1.98	0.0158	**0.8**
PreciControl ClinChem Multi 2	3.05	0.0267	**0.9**
Human Urine 1	0.435	0.0111	2.5
Human Urine 2	0.737	0.0112	1.5
Human Urine 3	1.23	0.0130	1.1
Human Urine 4	2.52	0.0215	0.9
Human Urine 5	3.30	0.0289	0.9

All data passed the predetermined acceptance criteria.

4.2. Analytical Sensitivity

4.2.1. Limit of Blank (LoB)

The Limit of Blank (LoB) of the Tina-quant Transferrin ver.2 (urine application) assay on the **cobas c** 501 was determined according to CLSI EP17-A2. LoB determines the highest measurement result that is likely to be observed for a blank sample with a stated probability. The LoB was determined as the 95th percentile of measurements of blank samples.

One analyte-free sample was measured on 3 lots of reagent in 10-fold determinations per run in 6 runs, distributed over 4 days, on 1 analyzer. In total, 60 measurements were obtained per reagent lot. Data analysis was based on determination of the 95th percentile of the 60 measured values.

LoB Claim: 0.10 mg/dL

4.2.2. Limit of Detection (LoD)

The Limit of Detection (LoD) of the Tina-quant Transferrin ver.2 (urine application) assay on the **cobas c** 501 analyzer was determined according to CLSI EP17-A2. The LoD corresponds to the lowest analyte concentration which can be detected (value above the LoB with a probability of 95%).

Five human urine samples with low-analyte concentration (approximately up to 4 times the specified LoB) were measured with 3 lots of reagent in 2-fold determinations per run in 6 runs, distributed over 4 days, on 1 analyzer. In total, 60 measurements were obtained per reagent lot.

LoD Claim: 0.15 mg/dL

4.2.3. Limit of Quantitation (LoQ)

The Limit of Quantitation (LoQ) of the Tina-quant Transferrin ver.2 (urine application) assay on the **cobas c** 501 was determined according to CLSI EP17-A2. LoQ determines the lowest amount of analyte in a sample that can be quantitatively determined with stated accuracy and experimental conditions. The LoQ was determined as the lowest concentration of analyte which can be quantified with a total error (% CV) of no more than 20%.

A low level sample set was prepared by diluting 5 human urine samples with analyte-free diluent (water). The low level sample set was tested in 5 replicates per sample on 4 days, 1 run per day, on 1 analyzer.

LoQ Claim: 0.22 mg/dL with 20% CV

4.2.4. Results and Conclusions

Table 4: LoB, LoD, and LoQ Experimental Determination

	Lot #1 Result (mg/dL)	Lot #2 Result (mg/dL)	Lot #3 Result (mg/dL)	Claim (mg/dL)
Limit of Blank (LoB)	0.0150	0.0130	0.0150	0.10
Limit of Detection (LoD)	0.0382	0.0331	0.0353	0.15
Limit of Quantitation (LoQ)	0.124	0.137	0.143	0.22

All data passed the predetermined acceptance criteria.

4.3. Linearity/Assay Reportable Range

4.3.1. Regression Analysis

The linearity study was conducted to determine whether the measurements across the claimed measuring range for each parameter have a linear relationship. The study was performed according to CLSI EP06-A.

Dilution series were prepared using the human urine sample pools with transferrin concentrations above the upper end of the measuring range. Dilutions were made using water. The dilution series contained 13 concentrations. Sample dilution levels were measured on 3 lots in triplicate on the **cobas c** 501 analyzer.

Linear regression analysis was done according to EP06-A.

In the first step, a linearity check was performed with 1st order (linear) regression and then with higher order models (quadratic and cubic). A linearity check was performed with a 1st order (linear) regression for reagent lots 1 and 2. A linearity check was performed with a 3rd order

(cubic) regression for reagent lot 3. The linear regression was not forced through the origin. The linear regression was not weighted.

4.3.2. Results and Conclusions

Table 5: Linearity Results

Reagent Lot	Linear Regression Equation (mg/dL)	Pearson Correlation Coefficient (r)	Measuring Range Claim (mg/dL)
1	y = 1.007x – 0.0189	0.9999	0.22 to 3.5
2	y = 1.008x – 0.0225	0.9999	0.22 to 3.5
3	y = 1.009x – 0.0236	0.9997	0.22 to 3.5

All data passed the predetermined acceptance criteria.

4.4. Endogenous Interference Studies

The purpose of this study was to evaluate endogenous substances for potential interference with the Tina-quant Transferrin ver.2 (urine application) assay measured on the **cobas c** 501 analyzer.

The effect on quantitation of analyte in the presence of potential endogenous interfering substances using Tina-quant Transferrin ver.2 (urine application) was determined on the **cobas c** 501 analyzer at 2 transferrin concentrations and a dilution set of the added interfering substances. Potential interfering substances evaluated include: albumin, calcium, citrate, creatinine, glucose, hemoglobin, IgG, magnesium, oxalate, phosphate, urea, uric acid and urobilinogen.

High concentrated stock solutions of the potential interfering substances were prepared in a suitable solvent. Two human urine pools were spiked with defined transferrin concentrations and divided into 2 aliquots. The potential interfering substance was added to 1 aliquot, while the other aliquot was mixed with the same amount of solvent without the potential interfering substance. A dilution series was prepared with 11 dilution steps for each potential interferent by diluting the spiked pool with the dilution pool. Three aliquots per level were tested in 1 run on 1 instrument and 1 lot.

The aliquot containing the potential interfering substance had the same transferrin concentration as the aliquot containing no interfering substance. When diluting those 2 aliquots, the transferrin

concentration remained constant while the concentration of the potential interferent varied. Thus the effect of increasing concentrations of potential interferent can be determined.

The medians of the measured results were compared to the expected results (aliquot with no potential interfering substance) and the recovery was determined (paired difference testing).

This procedure was repeated for each of the potential interfering substances.

4.4.1. Results and Conclusions

Table 6: Potentially Interfering Endogenous Substances and Test Concentrations

Potential Interferent	No Interference up to:	Claim
Albumin	Level 1: 5 g/L Level 2: 5 g/L	No interference ≤ 5000 mg/L
Calcium	Level 1: 9.92 mmol/L Level 2: 9.80 mmol/L	No interference ≤ 8 mmol/L
Citrate	Level 1: 11 mmol/L Level 2: 11 mmol/L	No interference ≤ 10 mmol/L
Creatinine	Level 1: 88 mmol/L Level 2: 88 mmol/L	No interference ≤ 44 mmol/L
Glucose	Level 1: 388 mmol/L Level 2: 388 mmol/L	No interference ≤ 111 mmol/L
Hemoglobin	Level 1: 146 mg/dL Level 2: 149 mg/dL	No significant interference up to a hemoglobin concentration of 100 mg/dL
Immunoglobulin (IgG)	Level 1: 1.1 g/L Level 2: 1.1 g/L	No interference ≤ 500 mg/L
Magnesium	Level 1: 75 mmol/L Level 2: 75 mmol/L	No interference ≤ 75 mmol/L
Oxalate	Level 1: 3.75 mmol/L Level 2: 3.75 mmol/L	No interference ≤ 2.2 mmol/L
Phosphate	Level 1: 130 mmol/L Level 2: 130 mmol/L	No interference ≤ 40 mmol/L
Urea	Level 1: 1500 mmol/L Level 2: 1800 mmol/L	No interference ≤ 1000 mmol/L
Uric Acid	Level 1: 6 mmol/L Level 2: 6 mmol/L	No interference ≤ 6 mmol/L
Urobilinogen	Level 1: 15 mg/dL Level 2: 15 mg/dL	No interference ≤ 15 mg/dL

All data passed the predetermined acceptance criteria.

4.5. Exogenous Interferences – Drugs

The purpose of this study was to evaluate drugs for potential interference to the Tina-quant Transferrin ver.2 (urine application) assay measured on the **cobas c** 501 analyzer.

Two human urine sample pools spiked with approximately 0.433 and 2.48 mg/dL transferrin concentrations were divided into 2 aliquots. One aliquot of each concentration was used as the reference sample for transferrin concentration and was not spiked with the drugs, but only the solvent for the drug.

The other aliquots, with either the high or low transferrin concentration, were spiked with the respective amount of drug. Each aliquot containing a defined transferrin concentration and spiked with drug was measured in triplicate in 1 run on 1 analyzer and 1 lot. The defined drug compounds were spiked into samples with concentrations according to EP07-A2 or higher.

4.5.1. Results and Conclusions

Table 7: Potentially Interfering Drugs and Test Concentration Results

Potential Drug Interferent	No interference up to:
Acetaminophen	3000 mg/L
Ascorbic acid	4000 mg/L
Cefoxitin	12000 mg/L
Gentamicin sulfate	400 mg/L
Ibuprofen	500 mg/L
Levodopa	1000 mg/L
Methyldopa	2000 mg/L
N-Acetylcysteine	10 mg/L
Ofloxacine	Interference Claim
Phenazopyridine	50 mg/L
Salicyluric acid	100 mg/L
Tetracycline	300 mg/L

All data passed the predetermined acceptance criterion except for ofloxacine.

Claim: Drugs: No interference was found at the therapeutic concentrations using common drug panels. Exceptions: Ofloxacine causes artificially high transferrin results.

4.6. Method Comparison to Predicate

A method comparison of the Tina-quant Transferrin ver.2 (urine application) assay on the **cobas c** 501 versus the predicate device, N Antisera to Human Transferrin (Siemens) on the BN ProSpec analyzer was conducted.

One hundred and seven routine fresh, never-frozen human urine samples were used in the method comparison testing. One of the 109 urine samples collected was removed due to a pH >8 and one was removed due to a measured value outside of the defined measuring range. No patient information was obtained. No samples were spiked or diluted.

The samples were tested in singlicate using the N Antisera to Human Transferrin assay (K053075) from Siemens on the BN ProSpec System and the Tina-quant Transferrin ver.2 (urine application) assay on the **cobas c** 501 analyzer.

The data was evaluated using Passing Bablok Regression analysis.

4.6.1. Results and Conclusions

Regression analysis results (mg/dL):

$$y = 1.007x + 0.0052, r = 0.995$$

Predetermined acceptance criteria for Method Comparison to the Predicate were met.

5. CLINICAL PERFORMANCE EVALUATION

Not applicable.

6. ADDITIONAL INFORMATION

6.1. Other Devices Required But Not Provided:

The Tina-quant Transferrin ver.2 (urine application) continues to use:

- Calibrator f. a. s. Proteins (K133330)
- PreciControl ClinChem Multi 1 (K133330)

- PreciControl ClinChem Multi 2 (K133330)
- Precinorm Protein (K133330)
- Precipath Protein (K133330)
- Diluent NaCl 9% (21 CFR § 864.4010, Class I 510(k) exempt)

7. CONCLUSIONS

The submitted information in this premarket notification supports a substantial equivalence decision.