June 19, 2019

Quidel Cardiovascular Inc.
Rachael Williamson
Senior Manager, Regulatory Affairs
9975 Summers Ridge Road
San Diego, CA 92121

Re: k182719
Trade/Device Name: Quidel Triage® TOX Drug Screen, 94600
Quidel Triage® MeterPro
Regulation Number: 21 CFR 862.3100
Regulation Name: Amphetamine test system
Regulatory Class: Class II
Product Code: DKZ, LAF, DIS, JXM, JXO, DJR, DJG, LDJ, LFG, KHO
Dated: June 13, 2019
Received: June 14, 2019

Dear Rachael Williamson:

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 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,

Kellie B. Kelm, Ph.D.
Acting Director
Division of Chemistry
and Toxicology Devices
OHT7: Office of In Vitro Diagnostics
and Radiological Health
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K182719

Device Name
Quidel Triage® TOX Drug Screen, 94600
Quidel Triage® MeterPro

Indications for Use *(Describe)*

Quidel Triage® TOX Drug Screen, 94600:
The Quidel Triage® TOX Drug Screen, 94600 is a fluorescence immunoassay to be used with the Quidel Triage® MeterPro for the qualitative determination of the presence of drugs and/or metabolites in human urine of up to 9 drug assays at or above the threshold concentrations. The threshold concentrations are provided below:

Abbreviation	Analyte	Calibrator	Cutoff
AMP	Amphetamines	d-Amphetamine	500 ng/mL
mAMP	Methamphetamines	d-Methamphetamine	500 ng/mL
BAR	Barbiturates	Butalbital	200 ng/mL
BZO	Benzodiazepines	Temazepam	200 ng/mL
COC	Cocaine	Benzoylecgonine	150 ng/mL
EDDP	Methadone Metabolite	EDDP	100 ng/mL
OPI	Opiates	Morphine	300 ng/mL
THC	Cannabinoids	11-nor-9-carboxy-Δ9-THC	50 ng/mL
TCA	Tricyclic Antidepressants	Desipramine	1000 ng/mL

This test provides only a preliminary test result. Clinical consideration and professional judgment must be applied to any drug test result, particularly in evaluating a preliminary positive result. A more specific alternate chemical method must be used to obtain a confirmed analytical result. Gas Chromatography / Mass Spectroscopy (GC/MS), Liquid Chromatography / Mass Spectroscopy / Mass Spectroscopy (LC-MS/MS) and High Performance Liquid Chromatography (HPLC) are common confirmatory methods.

Quidel Triage® MeterPro:
The Quidel Triage® MeterPro is a portable fluorescence instrument used to measure the results of tests manufactured by Quidel Cardiovascular Inc. The Quidel Triage® MeterPro can be used in a laboratory or in a point-of-care setting.

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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K182719

1. 510(K) SUMMARY

1.1. Date Prepared:

June 18, 2019

1.2. Purpose for Submission:

New device

1.3. Measurand:

Amphetamine, Methamphetamine, Barbiturates, Benzodiazepines, Cocaine, EDDP (2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine), Opiates, Cannabinoids, Tricyclic Antidepressants

1.4. Type of Test:

Qualitative, lateral flow immunofluorescence

1.5. Applicant:

Quidel Cardiovascular Inc.
9975 Summers Ridge Road
San Diego, California 92121
Telephone: 858-302-0334
Fax: 858-805-8622

Rachael S. Williamson (Submission Contact)

1.6. Proprietary and Established Names:

Quidel Triage® TOX Drug Screen, 94600
Quidel Triage® MeterPro

1.7. Regulatory Information:

Quidel Triage® TOX Drug Screen, 94600:

Product Code	Classification	Regulatory Section	Panel
DKZ	Class II	21 CFR 862.3100, Amphetamine test system	Toxicology (91)

Product Code	Classification	Regulatory Section	Panel
LAF	Class II	21 CFR 862.3610, Methamphetamine test system	Toxicology (91)
DIS	Class II	21 CFR 862.3150, Barbiturate test system	Toxicology (91)
JXM	Class II	21 CFR 862.3170, Benzodiazepine test system	Toxicology (91)
JXO	Class II	21 CFR 862.3250, Cocaine and cocaine metabolite test system	Toxicology (91)
DJR	Class II	21 CFR 862.3260, Methadone test system	Toxicology (91)
DJG	Class II	21 CFR 862.3650, Opiate test system	Toxicology (91)
LDJ	Class II	21 CFR 862.3870, Cannabinoid test system	Toxicology (91)
LFG	Class II	21 CFR 862.3910, Tricyclic antidepressant drugs test system	Toxicology (91)

Quidel Triage® MeterPro:

Product Code	Classification	Regulatory Section	Panel
KHO	Class I	21 CFR 862.2560, Fluorometer for clinical use	Clinical Chemistry

1.8. Intended Use:

Quidel Triage® TOX Drug Screen, 94600:
The Quidel Triage® TOX Drug Screen, 94600 is a fluorescence immunoassay to be used with the Quidel Triage® MeterPro for the qualitative determination of the presence of drugs and/or

metabolites in human urine of up to 9 drug assays at or above the threshold concentrations. The threshold concentrations are provided below:

Abbreviation	Analyte	Calibrator	Cutoff
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EDDP	Methadone Metabolite	EDDP	100 ng/mL
OPI	Opiates	Morphine	300 ng/mL
THC	Cannabinoids	11-nor-9-carboxy-Δ^9-THC	50 ng/mL
TCA	Tricyclic Antidepressants	Desipramine	1000 ng/mL

This test provides only a preliminary test result. Clinical consideration and professional judgment must be applied to any drug test result, particularly in evaluating a preliminary positive result. A more specific alternate chemical method must be used to obtain a confirmed analytical result. Gas Chromatography / Mass Spectroscopy (GC/MS), Liquid Chromatography / Mass Spectroscopy / Mass Spectroscopy (LC-MS/MS) and High Performance Liquid Chromatography (HPLC) are common confirmatory methods.

Quidel Triage® MeterPro:
The Quidel Triage® MeterPro is a portable fluorescence instrument used to measure the results of tests manufactured by Quidel Cardiovascular Inc. The Quidel Triage® MeterPro can be used in a laboratory or in a point-of-care setting.

1.9. Device Description:

Quidel Triage® TOX Drug Screen, 94600:
The Quidel Triage® TOX Drug Screen, 94600 is a single use test device and is used in conjunction with the Quidel Triage® MeterPro. The device contains murine monoclonal antibody conjugates and drug conjugates labeled with a fluorescent dye or immobilized on the solid phase and stabilizers. The testing device is inserted into and read by the Quidel Triage® MeterPro. Threshold concentrations are used to separate a negative result from a presumptive positive result.

Quidel Triage® MeterPro:
The Quidel Triage MeterPro is a portable fluorescence instrument used to measure the results of tests manufactured by Quidel Cardiovascular Inc. The Quidel Triage MeterPro can be used in a laboratory or in a point-of-care setting.

The Quidel Triage MeterPro uses a laser as a light source. Light from the laser hits a test device that has been inserted in the meter. This causes the fluorescent dye in the test device to give off energy. The more energy the fluorescent dye gives off, the stronger the signal.

1.10. Substantial Equivalence Information:

1. Predicate Device Name:

   GenPrime Drugs of Abuse (DOA) Reader System
   Immunalysis Barbiturates Urine Enzyme Immunoassay
   DRI Benzodiazepine Assay
   Immunalysis EDDP Specific Urine Enzyme Immunoassay
   Biosite Incorporated Triage TOX Drug Screen
   Biosite Incorporated Triage Meter

2. Predicate 510(k) Number:

   K130082, GenPrime Drugs of Abuse (DOA) Reader System
   K161714, Immunalysis Barbiturates Urine Enzyme Immunoassay
   K173963, DRI Benzodiazepine Assay
   K151395, Immunalysis EDDP Specific Urine Enzyme Immunoassay
   K043242, Biosite Incorporated Triage® TOX Drug Screen
   K973547, Biosite Incorporated Triage® Meter

3. Comparison with Predicate:

   Quidel Triage® TOX Drug Screen, 94600:

   Assays: Amphetamines (AMP), Methamphetamines (mAMP), Cocaine (COC), Opiates (OPI), and Cannabinoids (THC)

Similarities		
Item	**Proposed Device**	**Predicate Device**
Features	Quidel Triage® TOX Drug Screen, 94600 (Proposed)	GenPrime Drugs of Abuse (DOA) Reader System (K130082)
Intended Use	For the qualitative determination of drugs of abuse in human urine.	Same
Assay Type	Competitive assay, where concentration of drug is inversely related to the signal detected by the instrument.	Same

Similarities		
Item	**Proposed Device**	**Predicate Device**
Features	Quidel Triage® TOX Drug Screen, 94600 (Proposed)	GenPrime Drugs of Abuse (DOA) Reader System (K130082)
System Procedure	Sample is added to a single use test device which is then read by the instrument. The instrument is designed to read multiple assays at the same time.	Same
Specimen Type	Human urine	Same
Single-use Test Device	Yes	Same
Analyte Cutoffs (ng/mL)	AMP = 500 mAMP = 500 COC = 150 OPI = 300 THC = 50	AMP = 500 (OS Cup; SK Cup) MET = 500 (OS Cup; SK Cup) COC = 150 (OS Cup) MOP = 300 (SK Cup) THC = 50 (OS Cup; SK Cup)

Differences		
Item	**Proposed Device**	**Predicate Device**
Features	Quidel Triage® TOX Drug Screen, 94600 (Proposed)	GenPrime Drugs of Abuse (DOA) Reader System (K130082)
Analyte Cutoffs (ng/mL)	BAR = 200 BZO = 200 EDDP = 100 TCA = 1000 MTD, OXY, PCP are not panel assays and have no associated analyte cutoffs.	BAR = 300 (OS Cup) MTD = 300 (SK Cup) MOP = 2000 (SK Cup) PCP = 25 (SK Cup) BZO, EDDP, and TCA are not panel assays and have no associated cutoff
Test Device Format	Cassette	Cup
Storage	2-8°C	2-30°C
Detection method	Measures fluorescence of discreet measurement zones for each assay.	Measures density of visible lines against background on single-use test device.

Differences		
Item	**Proposed Device**	**Predicate Device**
Features	Quidel Triage® TOX Drug Screen, 94600 (Proposed)	GenPrime Drugs of Abuse (DOA) Reader System (K130082)
Test Time and Timing Method	Operator adds sample to test device and operates the instrument.	Operator manually times test development for 5 minutes and then operates the instrument.
Measurement Method	Scans the single-use test device to measure signals.	Scans the single-use test device to detect a signal.
Time to Results	Result interpretation occurs in approximately 15 minutes.	Results interpretation must occur between 5 and 60 minutes following specimen application
Output	Outputs are "POS" if the result is at or above the threshold concentration or "NEG" if the result is below the threshold concentration. The operator has the option to print the results. If connected, the MeterPro can transmit results to the laboratory or hospital information system.	Outputs "presumptive positive", "negative", and "invalid" test results on a graphic user interface displayed on a computer screen and automatically stores results along with test information. Operator has ability to print and/or export results.

The following cutoff values are being incorporated into the Quidel Triage® TOX Drug Screen, 94600 Test Device. The cutoff values have been modified to accommodate changes in the calibrator used to manufacture the Test Device for barbiturates and benzodiazepines. In addition, the proposed predicates are identified for the EDDP and TCA assays. The tables below provide the similarities and differences with the selected predicates.

Assay: Barbiturates (BAR)

Similarities		
Item	**Proposed Device**	**Predicate Device**
Features	Quidel Triage® TOX Drug Screen, 94600 (Proposed)	Immunalysis Barbiturates Urine Enzyme Immunoassay (K161714)
Intended Use	For the qualitative determination of drugs of abuse in human urine.	Same

Similarities		
Item	**Proposed Device**	**Predicate Device**
Features	Quidel Triage® TOX Drug Screen, 94600 (Proposed)	Immunalysis Barbiturates Urine Enzyme Immunoassay (K161714)
Specimen Type	Human urine	Same
Storage	2-8°C	Same
Measured Analyte	BAR	Same
Analyte Cutoff (ng/mL)	BAR = 200	Same

Differences		
Item	**Proposed Device**	**Predicate Device**
Features	Quidel Triage® TOX Drug Screen, 94600 (Proposed)	Immunalysis Barbiturates Urine Enzyme Immunoassay (K161714)
Intended Use	Not intended for semi-quantitative determination of the presence of Barbiturates in human urine.	For the semi-quantitative determination of the presence of Barbiturates in human urine.
Assay Type	Competitive assay, where concentration of drug is inversely related to the signal detected by the instrument.	Enzyme immunoassay
Antibody Type	Mouse monoclonal antibodies	Recombinant and monoclonal antibodies

Assay: Benzodiazepines (BZO)

Similarities		
Item	**Proposed Device**	**Predicate Device**
Features	Quidel Triage® TOX Drug Screen, 94600 (Proposed)	DRI Benzodiazepine Assay (K173963)
Intended Use	For the qualitative determination of drugs of abuse in human urine.	Same
Specimen Type	Human urine	Same
Storage	2-8°C	Same

Similarities		
Item	**Proposed Device**	**Predicate Device**
Features	Quidel Triage® TOX Drug Screen, 94600 (Proposed)	DRI Benzodiazepine Assay (K173963)
Analyte Cutoff (ng/mL)	BZO = 200	Same

Differences		
Item	**Proposed Device**	**Predicate Device**
Features	Quidel Triage® TOX Drug Screen, 94600 (Proposed)	DRI Benzodiazepine Assay (K173963)
Intended Use	Not intended for semi-quantitative determination of the presence of benzodiazepines and their metabolites in human urine.	For the semi-quantitative determination of the presence of benzodiazepines and their metabolites in human urine.
Assay Type	Competitive assay, where concentration of drug is inversely related to the signal detected by the instrument.	Homogenous enzyme immunoassay
Antibody Type	Mouse monoclonal antibodies	Polyclonal sheep antibody

Assay: 2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP)

Similarities		
Item	**Proposed Device**	**Predicate Device**
Features	Quidel Triage® TOX Drug Screen, 94600 (Proposed)	Immunalysis EDDP Specific Urine Enzyme Immunoassay (K151395)
Intended Use	For the qualitative determination of drugs of abuse in human urine.	Same
Specimen Type	Human urine	Same
Storage	2-8°C	Same
Assay calibrated	EDDP	Same
Measured Analyte	EDDP	Same
Analyte Cutoff (ng/mL)	EDDP = 100	Same

Differences		
Item	**Proposed Device**	**Predicate Device**
Features	Quidel Triage® TOX Drug Screen, 94600 (Proposed)	Immunalysis EDDP Specific Urine Enzyme Immunoassay (K151395)
Intended Use	Not intended for semi-quantitative determination of the presence of EDDP in human urine.	For the semi-quantitative determination of the presence of EDDP in human urine.
Assay Type	Competitive assay, where concentration of drug is inversely related to the signal detected by the instrument.	Homogenous enzyme immunoassay
Antibody Type	Mouse monoclonal antibodies	Recombinant fab antibodies
Analyte Cutoffs (ng/mL)	Not intended to have cutoffs available at 300 ng/mL and 1000 ng/mL	EDDP = 300 and 1000

Assay: Tricyclic Antidepressants (TCA)

Similarities		
Item	**Proposed Device**	**Predicate Device**
Features	Quidel Triage® TOX Drug Screen, 94600 (Proposed)	Triage® TOX Drug Screen (K043242)
Intended Use	For the qualitative determination of drugs of abuse in human urine.	Same
Assay Type	Competitive assay, where concentration of drug is inversely related to the signal detected by the instrument.	Same
Specimen Type	Human urine	Same
Storage	2-8°C	Same
Detection method	Measures fluorescence of discreet measurement zones for each assay.	Same
Assay calibrated	Desipramine	Same

Similarities		
Item	**Proposed Device**	**Predicate Device**
Features	Quidel Triage® TOX Drug Screen, 94600 (Proposed)	Triage® TOX Drug Screen (K043242)
Measured Analyte	TCA	Same
Analyte Cutoff (ng/mL)	TCA = 1000	Same

Differences		
Item	**Proposed Device**	**Predicate Device**
Features	Quidel Triage® TOX Drug Screen, 94600 (Proposed)	Triage® TOX Drug Screen (K043242)
Analytes	Amphetamines, Methamphetamines, Barbiturates, Benzodiazepines, Cocaine, Methadone Metabolite, Opiates, Cannabinoids (THC), and Tricyclic Antidepressants	Acetaminophen, Amphetamines, Methamphetamines, Barbiturates, Benzodiazepines, Cocaine, Opiates, Phencyclidine, THC, and Tricyclic Antidepressants

Quidel Triage® MeterPro:

Last, the proposed predicate for the Quidel Triage MeterPro is its predecessor the Triage Meter cleared under K973547.

Similarities		
Item	**Proposed Device**	**Predicate Device**
Features	Quidel Triage® MeterPro (Proposed)	Triage Meter (K973547)
Device Class	I	Same
Power supply	100-240 VAC, self-switching, or with 4 AA batteries	Same
Max. Voltage of ext. power supply	20 V	Same
Electrostatic protection to serial port	8 / 15 kV	Same
Number of serial ports	2 (by use of adapter)	Same
Printer	Integrated	Same

Similarities		
Item	**Proposed Device**	**Predicate Device**
Features	Quidel Triage® MeterPro (Proposed)	Triage Meter (K973547)
Sample ID	Manual input or external hand-held barcode scanner	Same
Barcode	Integrated barcode on each test device with lot specific information	Same
Time to result	Approximately 15 – 20 minutes	Same

Differences		
Item	**Proposed Device**	**Predicate Device**
Features	Quidel Triage® MeterPro (Proposed)	Predicate Device
Regulation	21 CFR 862.2560	21 CFR 862.2560 (KHO) 21 CFR 862.5680 (DDR) 21 CFR 862.1215 (JHX) 21 CFR 862.1215 (MMI)
Product Code	KHO	KHO, DDR, JHX, MMI
Sample Type	Whole blood, plasma or urine	Whole blood or plasma
Top meter housing	New top meter housing mold to provide a larger liquid crystal display (LCD) and two elastomer keypads	Small LCD with one single membrane keyboard

1.11. Standard/Guidance Document Referenced:

None referenced.

1.12. Test Principle:

The Quidel Triage TOX Drug Screen, 94600 is a test device utilizing the standard Triage technology. It is a competitive fluorescence immunoassay which contains all the reagents necessary for the qualitative detection, relative to an assigned threshold value, of the major urinary metabolites for the following substances in human urine: amphetamine (AMP), methamphetamine (mAMP), barbiturates (BAR), benzodiazepines (BZO), cocaine (COC), methadone/methadone metabolite (EDDP), opiates (OPI), tetrahydrocannabinol (THC), and tricyclic antidepressants (TCA).

The Test Device contains:

- Murine monoclonal antibodies against 9 targeted drugs or metabolites
- Fluorescently labeled antibodies
- Fluorescently labeled metabolites
- Solid phase
- Stabilizers

The test procedure involves the addition of a urine specimen to the sample port on the Test Device. After addition of the specimen, the urine passes through a filter. The specimen reacts with fluorescent antibody conjugates or with fluorescent drug conjugates and flows through the Test Device by capillary action. The presence of drug or drug metabolite in the urine specimen prevents binding of the fluorescent conjugates to the solid phase on the detection zone. Excess urine washes the unbound fluorescent conjugates from the detection lane into a waste reservoir.

The Test Device is inserted into the Quidel Triage MeterPro. The Quidel Triage MeterPro is programmed to perform the analysis after the specimen has reacted with the reagents in the Test Device. The analysis is based on the amount of fluorescence the Quidel Triage MeterPro detects within a measurement zone on the Test Device. The positive or negative results are displayed on the Quidel Triage MeterPro screen in about 15 minutes. All results are stored in the Quidel Triage MeterPro memory to display or print when needed. If connected, the Quidel Triage MeterPro can transmit results to the laboratory or hospital information system.

1.13. Performance Characteristics:

1. Analytical Performance

    a. Precision/Reproducibility:

    Each analyte for the precision study was tested at the following concentrations, as percentages of the cutoffs: A negative control, drug free, 25%, 50%, 75%, cutoff, 125%, 150%, 175%, and 200%. The panels were blinded and randomized prior to testing. Testing was performed at three (3) study sites. Three (3) operators conducted the testing at each study site. Each operator was assigned one test device lot and five (5) Triage MeterPro instruments to conduct the testing. Each operator tested ten (10) samples each day of testing. The ten (10) samples were run in duplicate two (2) times per day for twenty (20) days at each clinical site. Each device was read on one (1) Triage MeterPro. There were approximately seven hundred twenty (720) results per sample. The test results were interpreted as positive (POS) or negative (NEG) for each individual assay based on the assay specific cut-off concentration values. The results of the testing are summarized as follow for the test device.

Sample Concentration (ng/mL)	% of Cutoff	n	# Neg	# Pos
AMP (500 ng/mL)				

Sample Concentration (ng/mL)	% of Cutoff	n	# Neg	# Pos
Negative Control	0	720	720	0
0	0	720	720	0
126	-75	720	720	0
281	-50	716	712	4
395	-25	720	694	26
522	Cutoff	719	50	669
650	+25	722	2	720
760	+50	720	0	720
884	+75	704	0	704
991	+100	736	0	736
mAMP (500 ng/mL)				
Negative Control	0	720	720	0
0	0	736	736	0
130	-75	720	720	0
250	-50	720	720	0
366	-25	716	697	19
529	Cutoff	720	281	431
652	+25	719	12	707
742	+50	722	2	720
872	+75	720	0	720
961	+100	704	0	704
BAR (200 ng/mL)				
Negative Control	0	720	720	0
0	0	704	704	0
53	-75	736	736	0
108	-50	720	719	1
156	-25	720	689	31
192	Cutoff	716	111	605
233	+25	720	3	717
306	+50	719	0	719
355	+75	722	0	722
406	+100	720	0	720
BZO (200 ng/mL)				
Negative Control	0	720	720	0
0	0	720	720	0
58	-75	704	704	0
107	-50	736	735	1

Sample Concentration (ng/mL)	% of Cutoff	n	# Neg	# Pos
166	-25	720	626	94
219	Cutoff	720	318	402
259	+25	716	9	707
306	+50	720	0	720
378	+75	719	0	719
399	+100	722	0	722
COC (150 ng/mL)				
Negative Control	0	720	720	0
0	0	716	716	0
41	-75	720	720	0
76	-50	719	719	0
119	-25	722	519	203
157	Cutoff	720	26	694
185	+25	704	0	704
218	+50	736	0	736
267	+75	720	0	720
300	+100	720	0	720
EDDP (100 ng/mL)				
Negative Control	0	720	720	0
0	0	722	722	0
29	-75	720	720	0
52	-50	704	702	2
85	-25	736	645	91
111	Cutoff	720	126	594
136	+25	720	5	715
143	+50	716	0	716
174	+75	720	0	720
204	+100	719	0	719
OPI (300 ng/mL)				
Negative Control	0	720	720	0
0	0	720	720	0
87	-75	719	719	0
165	-50	722	722	0
231	-25	720	715	5
344	Cutoff	704	197	507
426	+25	736	5	731
480	+50	720	0	720

Sample Concentration (ng/mL)	% of Cutoff	n	# Neg	# Pos
548	+75	720	0	720
589	+100	716	0	716
THC (50 ng/mL)				
Negative Control	0	720	720	0
0	0	720	720	0
12	-75	716	716	0
26	-50	720	717	3
39	-25	719	676	43
54	Cutoff	722	163	559
65	+25	720	1	719
78	+50	704	4	700
91	+75	736	1	735
103	+100	720	0	720
TCA (1,000 ng/mL)				
Negative Control	0	720	720	0
0	0	719	719	0
236	-75	722	722	0
498	-50	720	719	1
741	-25	704	618	86
996	Cutoff	736	218	518
1,395	+25	720	5	715
1,577	+50	720	1	719
1,716	+75	716	0	716
2,195	+100	720	0	720

b. Linearity/Assay Reportable Range:

Not applicable. These devices are intended for qualitative use only.

c. Traceability, Stability, Expected Values

Cold Storage Stability

A shelf-life stability study of the test was performed and the results showed that devices are stable for 3 months when stored in cold storage (2°C to 8°C). Real time stability studies are ongoing and shelf life will be extended based upon data meeting the acceptance criteria.

Room Temperature Stability
A shelf-life stability study of the test was performed and the results showed that devices are stable for 14 days when stored at room temperature (20°C to 24°C). Room temperature stability studies are ongoing and shelf life will be extended based upon data meeting the acceptance criteria.

Patient Sample Handling Stability
A patient sample handling stability study of the test was performed and patient sample results were found to be stable when used within 36 hours of sample collection at room temperature and within four (4) days when stored refrigerated. No more than a single freeze/thaw cycle is recommended.

d. Detection Limit:

See assay cutoff characterization data in Section 15.13.1.f. below for assay performance around the claimed cutoff concentrations.

e. Analytical Specificity:

To test cross-reactivity, drug metabolites and other compounds that may be present in human urine samples were tested using nine (9) lots of Quidel Triage TOX Drug Screen, 94600 Test Devices. The following is a summary of the cross-reactivity study. The individual assays are calibrated against the compounds marked with an asterisk (*).

AMP (Cutoff = 500 ng/mL)	**Results Positive at (ng/mL)**	**% Cross-Reactivity**
3,4-Methylenedioxyamphetamine (MDA)	1,850	27.0
3,4-Methylenedioxyethylamphetamine (MDEA)	>200,000	0.0
3,4-Methylenedioxymethamphetamine (MDMA)	>200,000	0.0
d,l-1-(3,4-Methylenedioxyphenyl)-2-Butanamine (BDB)	1,500	33.3
d,l-Amphetamine	1,000	50.0
d,l-Phenylpropanolamine	>200,000	0.0
d-Ephedrine	>200,000	0.0
d-Amphetamine*	500	100.0

AMP (Cutoff = 500 ng/mL)	Results Positive at (ng/mL)	% Cross-Reactivity
d-Pseudoephedrine	>200,000	0.0
l-Amphetamine	3,000	16.7
l-Ephedrine	>200,000	0.0
Phentermine	>200,000	0.0
p-Chloroamphetamine (PCA)	2,000	25.0
p-Hydroxyamphetamine	3,500	14.3
p-Methoxyamphetamine (PMA)	1,750	28.6
Tyramine	95,000	0.5
β-phenylethylamine	30,000	1.7

mAMP (Cutoff = 500 ng/mL)	Results Positive at (ng/mL)	% Cross-Reactivity
3,4-Methylenedioxyamphetamine (MDA)	>200,000	0.0
3,4-Methylenedioxyethylamphetamine (MDEA)	2,300	21.7
3,4-Methylenedioxymethamphetamine (MDMA)	750	66.7
d,l-1-(3,4-Methylenedioxyphenyl)-2-Butanamine (BDB)	25,000	2.0
d,l-Methyl-1(3,4-Methylenedioxyphenyl)2-Butanamine (MBDB)	500	100.0
d-Methamphetamine*	500	100.0
d-Amphetamine	>200,000	0.0
d-Ephedrine	>150,000	0.0
Ethylamphetamine	7,000	7.1
Fenfluramine	5,000	10.0
l-Amphetamine	>200,000	0.0
l-Ephedrine	>200,000	0.0
l-Methamphetamine	>200,000	0.0
Isometheptene	50,000	1.0
Mephentermine	25,000	2.0
p-Hydroxymethamphetamine	1,000	50.0
p-Methoxyamphetamine (PMA)	>200,000	0.0
p-Methoxymethamphetamine (PMMA)	2,200	22.7
Propylamphetamine	>200,000	0.0

BAR (Cutoff = 200 ng/mL)	Results Positive at (ng/mL)	% Cross-Reactivity
Allobarbital	300	66.7
Alphenal	400	50.0
Amobarbital	250	80.0
Aprobarbital	300	66.7
Barbital	300	66.7
Butabarbital	200	100.0
Butalbital*	200	100.0
Butethal	100	200.0
Cyclopentobarbital	200	100.0
Hexobarbital	90,000	0.2
Mephobarbital	3,000	6.7
Phenallylmal	400	50.0
Pentobarbital	500	40.0
Phenobarbital	230	87.0
Secobarbital	700	28.6
Thiopental	80,000	0.3%

BZO (Cutoff = 200 ng/mL)	Results Positive at (ng/mL)	% Cross-Reactivity
Alprazolam	100	200.0
Alprazolam, -OH	150	133.3
Bromazepam	750	26.7
Chlordiazepoxide	8,000	2.5
Clobazam	750	26.7
Clonazepam	650	30.8
Clonazepam, 7-amino	26,000	0.8
Clorazepate	1,200	16.7
Delorazepam	350	57.1
Demoxepam	10,000	2.0
Desalkylflurazepam	200	100.0

BZO (Cutoff = 200 ng/mL)	Results Positive at (ng/mL)	% Cross-Reactivity
Diazepam	125	160.0
Estazolam	400	50.0
Flunitrazepam	200	100.0
Flunitrazepam, 7-amino	6,000	3.3
Flurazepam	80	250.0
Halazepam	250	80.0
Lorazepam	200	100.0
Lorazepam glucuronide	300	66.7
Lormetazepam	100	200.0
Medazepam	9,000	2.2
Midazolam	200	100.0
Nitrazepam	2,600	7.7
Nitrazepam, 7-amino	>150,000	0.0
Norchlordiazepoxide	7,000	2.9
Nordiazepam	1,100	18.2
Oxazepam	2,500	8.0
Oxazepam glucuronide	1,250	16.0
Prazepam	350	57.1
Temazepam*	200	100.0
Temazepam glucuronide	300	66.7
Triazolam	100	200.0

COC (Cutoff = 150 ng/mL)	Results Positive at (ng/mL)	% Cross-Reactivity
Benzoylecgonine*	150	100.0
Cocaethylene	>200,000	0.0
Cocaine	50,000	0.3
Ecgonine	>200,000	0.0
Ecgonine methyl ester	>200,000	0.0
m-Hydroxybenzoylecgonine	400	37.5
Norcocaine	>200,000	0.0

EDDP (Cutoff = 100 ng/mL)	Results Positive at (ng/mL)	% Cross-Reactivity
EDDP*	100	100.0
EMDP	40,000	0.3
l-iso-methadone	>100,000	0.0
l-methadone	160,000	0.1
d-methadone	>200,000	0.0
d/l-methadone	>200,000	0.0
l-β-Acetylmethadol (LAAM)	>200,000	0.0

OPI (Cutoff = 300 ng/mL)	Results Positive at (ng/mL)	% Cross-Reactivity
6-Acetylcodeine	200	150.0
6-Acetylmorphine	200	150.0
Buprenorphine	>40,000	0.0
Codeine	300	100.0
Diacetylmorphine	200	150.0
Dihydrocodeine	120	250.0
Ethylmorphine	300	100.0
Hydrocodone	700	42.9
Hydromorphone	1,100	27.3
Levorphanol	25,000	1.2
Morphine*	300	100.0
Morphine-3-glucuronide	300	100.0
Nalorphine	3,000	10.0
Naloxone	>230,000	0.0
Naltrexone	>200,000	0.0
Norbuprenorphine	>200,000	0.0
Norcodeine	>200,000	0.0
Normorphine	>300,000	0.0
Oxycodone	50,000	0.6
Oxymorphone	100,000	0.3
Thebaine	35,000	0.9

THC (Cutoff = 50 ng/mL)	Results Positive at (ng/mL)	% Cross-Reactivity
(+/-) 11-hydroxy- Δ^9-THC	1,500	3.3
11-nor- Δ^8-THC-COOH	100	50.0
11-nor-9 carboxy-Δ^9-THC*	50	100.0
11-nor-9 carboxy-Δ^9-THC-glucuronide	17,000	0.3
Cannabidiol	>200,000	0.0
Cannabinol, Δ^8-	3,000	1.7
Cannabinol, Δ^9-	3,000	1.7
Tetrahydrocannabinol	3,000	1.7

TCA (Cutoff = 1,000 ng/mL)	Results Positive at (ng/mL)	% Cross-Reactivity
Amitriptyline	600	166.7
Amitriptyline metabolite	300	333.3
Chlorpromazine	>400,000	0.0
Chlorprothixene	40,000	2.5
Clomipramine	10,000	10.0
Cyclobenzaprine	1,400	71.4
Desipramine*	1,000	100.0
Doxepin	1,300	76.9
Imipramine	600	166.7
Maprotiline	240,000	0.4
Nordoxepin	1,500	66.7
Nortriptyline	900	111.1
Perphenazine	175,000	0.6
Phenothiazine	280,000	0.4
Promazine	35,000	2.9
Promethazine	>200,000	0.0
Protriptyline	2,500	40.0%
Thiothixene	>100,000	0.0%
Trimeprazine	83,500	1.2%
Trimipramine	3,800	26.3%

Cross-reactivity

Potential interference from pharmaceutical compounds was tested by spiking the listed compounds at a concentration of 100 µg/mL into drug-free urine containing the target drug concentrations at 50% below and 50% above the threshold cutoff level. The following compounds, arranged in alphabetical order, were found not to cross react when tested at concentrations up to at least 100 µg/mL. For the pharmaceutical compounds where interference was observed, the highest concentration that did not cause interference is indicated along with the assay in which it interfered.

5-(4-Hydroxyphenyl)-5-phenylhydantoin	Doxepin (0.65 µg/mL; TCA)	O-desmethylvenlafaxine
Acetaminophen	Dronabinol (1 µg/mL; THC)	*d,l*-Octopamine
Acetophenetidin	Droperidol	Ofloxacin
Acetopromazine (maleate salt)	Duloxetine	Olanzapine
Amantadine	Efavirenz	Oxalic Acid
Amoxicillin	L-Epinephrine	Oxaprozin
Ampicillin	Fenfluramine (2 µg/mL; AMP and mAMP)	Pantoprazole
Aspirin (acetylsalicylic acid)	Fenproporex	Papaverine
Atenolol	Flunitrazepam (0.2 µg/mL; BZO)	Pentazocine
Atorvastatin	Fluoxetine	Pericyazine
Benzocaine	Gamma-Hydroxybutyrate	Phenelzine
Benzphetamine	Glutethimide (10 µg/mL; BAR)	Phenethylamine (2-Phenylethylamine) (6 µg/mL; AMP)
Benzydamine	Haloperidol	Phenmetrazine (37.5 µg/mL; TCA)
Buprenorphine	Ibuprofen	Phentermine
Benztropine Mesylate	Ketamine	Phenylephrine
Bupropion	Ketorolac Tromethamine	Phenylpropanolamine
Butyrophenone	Labetalol	Promethazine
Carbamazepine	Levofloxacin	*d/l* -Propranolol
Chlorpheniramine	Levorphanol (12.5 µg/mL; OPI)	*d*-Pseudoephedrine (50 µg/mL; THC)
Cimetidine	Meperidine	Quetiapine
Citalopram	Meprobamate	Quinacrine (50 µg/mL; THC)

Clobenzorex	Mesoridazine Besylate	Quinine
Clomipramine (5 µg/mL; TCA)	Methaqualone	Ranitidine
Clonidine	Methoxyphenamine	Rifampin
Cotinine [l-Cotinine]	Methylphenidate	Ritodrine
Cyproheptadine	Nalbuphine	Selegiline
Dexamphetamine (0.4 µg/mL; AMP)	Nalmefene	Sertraline
Dextromethorphan	Naloxone	Thioridazine
Dextrorphan Tartrate	Naltrexone	Tramadol
Dimethylamine	Naproxen [(S)-6-Methoxy-α-methyl-2 Naphthaleneacetic acid]	Tranylcypromine
Diphenhydramine	N-desmethylvenlafaxine	Trimethobenzamide
Dopamine	Niacinamide	Tyramine (25 µg/mL; AMP)
Dothiepin (0.7 µg/mL; TCA)	Nicotine	Verapamil
Doxylamine Succinate	Norpseudoephedrine (25 µg/mL; AMP)	Zolpidem

Exogenous Interference

Potential interference from exogenous compounds was tested by spiking the listed compounds into treated drug-free urine containing the target drug concentrations at 50% below and 50% above the threshold cutoff level. The following exogenous compounds were found not to interfere with test results when tested up to the concentrations identified in the table below.

Interfering Substance	Concentration
Acetaminophen	1 mg/mL
Acetone	5 mg/mL
Acetylsalicylic Acid	1 mg/mL
Ascorbic Acid	15 mg/mL
Caffeine	0.125 mg/mL
Ethanol	5 mg/mL
Fluoxetine	0.5 mg/mL
Hippuric Acid	10 µg/mL
Ibuprofen	0.75 mg/mL
Ketamine	25 mg/mL
Oxalic Acid	7 mg/mL
Riboflavin	75 µg/mL

Interfering Substance	Concentration
Scopolamine	62.5 µg/mL

Endogenous Interference

Potential interference from endogenous compounds was tested by spiking the listed compounds into drug-free urine containing the target drug concentrations at 50% below and 50% above the threshold cutoff level. The following endogenous compounds were found not to interfere with test results when tested up to the concentrations identified in the table below.

Interfering Substance	Concentration
Bilirubin	2.5 µg/mL
Creatinine	2.5 mg/mL
Dextrose	20 mg/mL
Gamma Globulin	5 mg/mL
Hemoglobin	1.2 mg/mL
Human Serum Albumin	5 mg/mL
Sodium Chloride	30 mg/mL
Urea	30 mg/mL

Specific gravity and pH

The effect of specific gravity for each analyte was evaluated by testing positive and negative samples at specific gravities ranging from 1.003 to 1.030 g/mL. No interference was observed for all specific gravities tested.

The effect of pH for each analyte was evaluated by testing positive and negative samples over a range of pH levels of 4.0 to 9.0. The Quidel Triage TOX Drug Screen, 94600 has been validated with specimens that have a pH range of 4.0 – 9.0, and no excessive interference was observed for each of the assays. In the case of the TCA assay, there was evidence that increasing urine pH levels at the top of the validated range could have an impact on positive control sample results as the assay cutoff of 1,000 ng/mL was approached. Specimens tested outside of the validated pH range may yield inaccurate results.

Operating Temperature

The effect of operating temperature for each analyte was evaluated by testing positive and negative samples at temperatures ranging from 16°C to 30°C (61°F to 86°F). Even though reasonable performance was found for the whole temperature range, non-conformance beyond the set specifications was observed for the cocaine, methamphetamine and opiate assays at the extremes of the temperature range. The Quidel Triage TOX Drug Screen, 94600 has been validated for an operating temperature range from 18°C to 28°C (64°F to 82°F).

Operating Humidity

The effect of operating humidity for each analyte was evaluated by testing positive and negative samples at relative humidities (RH) ranging from ≤ 10 %RH to 85 %RH. The Quidel Triage TOX Drug Screen, 94600 was validated for an operating relative humidity (RH) range from 10 %RH to 85 %RH and met the specifications set for all assays.

f. Assay cut-off:

Each analyte for the cutoff characterization study was tested at the following concentrations: 0, 25%, 50%, 75%, 100%, +125%, +150%, +175% and +200% of the specific cutoff for each drug assay. Testing was performed using 3 lots of Quidel Triage TOX Drug Screen, 94600 Test Devices and was performed by 3 operators. The results are summarized as follows for each analyte.

Amphetamine (AMP) 500 ng/mL		
Concentration (ng/mL)	% of cutoff	Results #Neg/#Pos
Negative Control	0%	315/0
0	0%	315/0
125	25%	315/0
250	50%	315/0
375	75%	313/2
500	100%	49/266
625	125%	1/314
750	150%	0/315
875	175%	0/315
1000	200%	0/315

Methamphetamine (mAMP) 500 ng/mL		
Concentration (ng/mL)	**% of cutoff**	**Results #Neg/#Pos**
Negative Control	0%	315/0
0	0%	315/0
125	25%	315/0
250	50%	315/0
375	75%	312/3
500	100%	127/188

Methamphetamine (mAMP) 500 ng/mL		
625	125%	11/304
750	150%	2/313
875	175%	0/315
1000	200%	0/315

Barbiturates (BAR) 200 ng/mL		
Concentration (ng/mL)	% of cutoff	Results #Neg/#Pos
Negative Control	0%	315/0
0	0%	315/0
50	25%	315/0
100	50%	315/0
150	75%	309/6
200	100%	78/237
250	125%	1/314
300	150%	1/314
350	175%	0/315
400	200%	0/315

Benzodiazepines (BZO) 200 ng/mL		
Concentration (ng/mL)	**% of cutoff**	**Results #Neg/#Pos**
Negative Control	0%	315/0
0	0%	315/0
50	25%	315/0
100	50%	315/0
150	75%	296/19
200	100%	242/73
250	125%	3/312
300	150%	0/315
350	175%	0/315
400	200%	0/315

Cocaine (COC) 150 ng/mL		
Concentration (ng/mL)	% of cutoff	Results #Neg/#Pos
Negative Control	0%	315/0
0	0%	315/0
37.5	25%	315/0
75	50%	315/0
112.5	75%	279/36
150	100%	10/305
187.5	125%	1/314
225	150%	0/315
262.5	175%	0/315
300	200%	0/315

Methadone Metabolite (EDDP) 100 ng/mL		
Concentration (ng/mL)	% of cutoff	Results #Neg/#Pos
Negative Control	0%	315/0
0	0%	315/0
25	25%	315/0
50	50%	315/0
75	75%	315/0
100	100%	115/200
125	125%	11/304
150	150%	0/315
175	175%	0/315
200	200%	0/315

Opiates (OPI) 300 ng/mL		
Concentration (ng/mL)	**% of cutoff**	**Results #Neg/#Pos**
Negative Control	0%	315/0
0	0%	315/0
75	25%	315/0
150	50%	315/0

Opiates (OPI) 300 ng/mL		
225	75%	315/0
300	100%	132/183
375	125%	1/314
450	150%	0/315
525	175%	0/315
600	200%	0/315

Cannabinoids (THC) 50 ng/mL		
Concentration (ng/mL)	% of cutoff	Results #Neg/#Pos
Negative Control	0%	315/0
0	0%	315/0
12.5	25%	315/0
25	50%	315/0
37.5	75%	295/20
50	100%	20/295
62.5	125%	0/315
75	150%	0/315
87.5	175%	0/315
100	200%	0/315

Tricyclic Antidepressants (TCA) 1000 ng/mL		
Concentration (ng/mL)	**% of cutoff**	**Results #Neg/#Pos**
Negative Control	0%	315/0
0	0%	315/0
250	25%	315/0
500	50%	315/0
750	75%	300/15
1000	100%	161/154
1250	125%	5/310
1500	150%	1/314
1750	175%	0/315
2000	200%	0/315

2. Comparison studies:

   a. Method comparison with reference method:

      A method comparison study was conducted using unaltered urine specimens and comparing results from the Quidel Triage TOX Drug Screen, 94600 to a reference method. Results are summarized below.

Quidel Triage TOX Drug Screen, 94600 Test Results vs GC/MS or LC-MS/MS Values

AMP (Cutoff = 500 ng/mL)					
		Reference Method Result by GC/MS or LC-MS/MS Value			
Drug	**Quidel Triage TOX Drug Screen, 94600**	**Negative (<50% of threshold)**	**Near Threshold Negative (within 50% below threshold)**	**Near Threshold Positive (within 50% above threshold)**	**Positive (>150% of threshold)**
AMP	Negative	99	11	**2[a]**	**2[b]**
	Positive	0	0	8	98

[a] Patient specimens with Specimen IDs 569740 and 575202 were found to be negative despite a near threshold positive result

[b] Patient specimens with Specimen IDs 570964 and 572667 were found to be negative despite a high positive result

Discordant sample resolution

Assay	**Cutoff Value (ng/mL)**	**Specimen ID**	**Quidel Triage TOX DS 94600 Result (POS/NEG)**	**Drug/Metabolite Detected**	**GC/MS or LC/MS/MS value (ng/mL)**
AMP	500	569740[a]	False Negative	Amphetamine	697
AMP	500	575202[a]	False Negative	Amphetamine	745
AMP	500	570964[b]	False Negative	Amphetamine	1003
AMP	500	572667[b]	False Negative	Amphetamine	1359

[b] The Quidel Triage TOX Drug Screen, 94600 has 100.0% cross-reactivity to the d-amphetamine isomer and 16.7% cross-reactivity to the l-amphetamine isomer, resulting in negative screening results even with amphetamine levels above the cutoff concentration of 500 ng/mL. A specimen with high levels of the l-amphetamine isomer may be associated with prescription use of medications containing amphetamines or compounds that metabolize to amphetamines. A summary of the results for the patient specimens containing both isomers is presented in the table below. After adjudication, Specimen ID 570964 would be classified as "near threshold" negative and would not be classified as a discordant result. Specimen ID 572667 would be classified as a "near threshold" positive patient specimen (within 10.8% of the assay threshold).

Specimen ID	Quidel Triage TOX Drug Screen, 94600 AMP Assay Cutoff (ng/mL)	Initial Value deter-mined by LC-MS/MS (ng/mL)	Initial Quidel Triage TOX Drug Screen, 94600 AMP Assay Result	Isomeric Composition (%)		*Isomeric Abundance* (ng/mL)		Effective Amphetamine (ng/mL)*	Adjudicated Quidel Triage TOX Drug Screen, 94600 AMP Assay Result
				% *d*-Amphetamine	% *l*-Amphetamine	*d*-Amphetamine	*l*-Amphetamine		
570964[b]	500	1003	False Negative	35.3	64.7	354	649	463	Negative
572667[b]	500	1359	False Negative	28.9	71.1	393	966	554	False Negative

mAMP (Cutoff = 500 ng/mL)					
		Reference Method Result by GC/MS or LC-MS/MS Value			
Drug	**Quidel Triage TOX Drug Screen, 94600**	**Negative (<50% of threshold)**	**Near Threshold Negative (within 50% below threshold)**	**Near Threshold Positive (within 50% above threshold)**	**Positive (>150% of threshold)**
mAMP	Negative	99	5	**5[d]**	**7[e]**
	Positive	0	**5[c]**	6	91

[c] Patient specimens with Specimen IDs 578510, 579777, 579705, 579727, and 579806 were found to be positive despite a near threshold negative result

[d] Patient specimens with Specimen IDs 586313, 586723, 579791, 586280 and 586293 were found to be negative despite a near threshold positive result

[e] Patient specimens with Specimen IDs 586276, 586269, 586264, 586282, 586275, 586300, and 579757 were found to be negative despite a high positive result

Discordant sample resolution

Assay	Cutoff Value (ng/mL)	Specimen ID	Quidel Triage TOX DS 94600 Result (POS/NEG)	Drug/Metabolite Detected	GC/MS or LC/MS/MS value (ng/mL)
mAMP	500	578510[c]	False Positive	Methamphetamine	325
mAMP	500	579777[c]	False Positive	Methamphetamine	402
mAMP	500	579705[c]	False Positive	Methamphetamine	445
mAMP	500	579727[c]	False Positive	Methamphetamine	490
mAMP	500	579806[c]	False Positive	Methamphetamine	495
mAMP	500	586313[d]	False Negative	Methamphetamine	535
mAMP	500	586273[d]	False Negative	Methamphetamine	555
mAMP	500	579791[d]	False Negative	Methamphetamine	588

Assay	Cutoff Value (ng/mL)	Specimen ID	Quidel Triage TOX DS 94600 Result (POS/NEG)	Drug/Metabolite Detected	GC/MS or LC/MS/MS value (ng/mL)
mAMP	500	586280[d]	False Negative	Methamphetamine	633
mAMP	500	586293[d]	False Negative	Methamphetamine	673
mAMP	500	586276[e]	False Negative	Methamphetamine	831
mAMP	500	586269[e]	False Negative	Methamphetamine	937
mAMP	500	586264[e]	False Negative	Methamphetamine	940
mAMP	500	586282[e]	False Negative	Methamphetamine	984
mAMP	500	586275[e]	False Negative	Methamphetamine	990
mAMP	500	586300[e]	False Negative	Methamphetamine	1028
mAMP	500	579757[e]	False Negative	Methamphetamine	1568

[e] The specimens contained both the d-methamphetamine and l-methamphetamine isomers. The initial LC-MS/MS reference method was unable to distinguish between the two enantiomeric forms. The Quidel Triage TOX Drug Screen, 94600 has 100.0% cross-reactivity to the d-methamphetamine isomer and 0.0% cross-reactivity to the l-methamphetamine isomer, resulting in negative screening results even with methamphetamine levels above the cutoff concentration of 500 ng/mL. A specimen with high levels of the l-methamphetamine isomer may be associated with prescription use of medications that contain methamphetamine or compounds that metabolize into methamphetamines. A summary of the results for the patient specimens containing both isomers is presented in the table below. After adjudication, Specimen IDs 586282, 586275 and 586300 were found to be negative despite a near threshold positive result (all within 8.6% of the assay threshold).

Specimen ID	Reference Laboratory 1 LC-MS/MS Confirmatory Value (ng/mL)	Quidel Triage TOX Drug Screen, 94600 Threshold Concentration (ng/mL)	Quidel Triage TOX Drug Screen, 94600 Result	Reference Laboratory 2 Results		Adjudicated Quidel Triage TOX Drug Screen, 94600 Result
				% d-Isomer	Concentration d-Isomer (ng/mL)	
586276[e]	831	500	False Negative	52.3	434.6	Negative
586269[e]	937	500	False Negative	52.8	494.7	Negative
586264[e]	940	500	False Negative	52.9	497.3	Negative
586282[e]	984	500	False Negative	52.2	513.6	False Negative
586275[e]	990	500	False Negative	52.3	517.8	False Negative
586300[e]	1028	500	False Negative	52.8	542.8	False Negative
579757[e]	1568	500	False Negative	19.9	312.0	Negative

BAR (Cutoff = 200 ng/mL)					
		Reference Method Result by GC/MS or LC-MS/MS Value			
Drug	**Quidel Triage TOX Drug Screen, 94600**	**Negative (<50% of threshold)**	**Near Threshold Negative (within 50% below threshold)**	**Near Threshold Positive (within 50% above threshold)**	**Positive (>150% of threshold)**
BAR	Negative	99	3	0	0
	Positive	0	**8**[f]	11	97

[f] Patient specimens with Specimen IDs 582858, 575082, 575081, 575079, 586932, 575085, 575084, and 575095 were found to be positive despite a near threshold negative result

Discordant sample resolution

Assay	Cutoff Value (ng/mL)	Specimen ID	Quidel Triage TOX DS 94600 Result (POS/NEG)	Drug/Metabolite Detected	GC/MS or LC/MS/MS value (ng/mL)
BAR	200	582858[f]	False Positive	Phenobarbital	120
BAR	200	575082[f]	False Positive	Phenobarbital	172
BAR	200	575081[f]	False Positive	Butalbital	150
BAR	200	575079[f]	False Positive	Butalbital	151
BAR	200	586932[f]	False Positive	Amobarbital	164
BAR	200	575085[f]	False Positive	Butalbital	165
BAR	200	575084[f]	False Positive	Phenobarbital	210
BAR	200	575095[f]	False Positive	Butalbital	197

BZO (Cutoff = 200 ng/mL)					
		Reference Method Result by GC/MS or LC-MS/MS Value			
Drug	**Quidel Triage TOX Drug Screen, 94600**	**Negative (<50% of threshold)**	**Near Threshold Negative (within 50% below threshold)**	**Near Threshold Positive (within 50% above threshold)**	**Positive (>150% of threshold)**
BZO	Negative	99	1	**1**[h]	0
	Positive	0	**10**[g]	10	99

[g] Patient specimens with Specimen IDs 586239, 586234, 586235, 582865, 570784, 569935, 585873, 570860, 570941, and 578527 were found to be positive despite a near threshold negative result

[h] Patient specimen with Specimen ID 578563 was found to be negative despite a near threshold positive result

Discordant sample resolution

Assay	Cutoff Value (ng/mL)	Specimen ID	Quidel Triage TOX DS 94600 Result (POS/NEG)	Drug/Metabolite Detected	GC/MS or LC/MS/MS value (ng/mL)
BZO	200	586239[g]	False Positive	Alprazolam-OH	79
BZO	200	586234[g]	False Positive	Alprazolam-OH	80
BZO	200	586235[g]	False Positive	Alprazolam-OH	86
BZO	200	582865[g]	False Positive	7-aminoclonazepam	293
				Lorazepam	53
				Oxazepam	379
BZO	200	570784[g]	False Positive	7-aminoclonazepam	1134
				Nordiazepam	63
				Oxazepam	124
				Temazepam	90
BZO	200	569935[g]	False Positive	Nordiazepam	68
				Oxazepam	244
				Temazepam	93
BZO	200	585873[g]	False Positive	Alprazolam-OH	105
				7-aminoclonazepam	2500
BZO	200	570860[g]	False Positive	Nordiazepam	83
				Oxazepam	218
				Temazepam	126
BZO	200	570941[g]	False Positive	Alprazolam-OH	126
BZO	200	578527[g]	False Positive	Alprazolam-OH	129
				7-aminoclonazepam	146
BZO	200	578563[h]	False Negative	Lorazepam	214

COC (Cutoff = 150 ng/mL)					
		Reference Method Result by GC/MS or LC-MS/MS Value			
Drug	**Quidel Triage TOX Drug Screen, 94600**	**Negative (<50% of threshold)**	**Near Threshold Negative (within 50% below threshold)**	**Near Threshold Positive (within 50% above threshold)**	**Positive (>150% of threshold)**
COC	Negative	99	5	0	0
	Positive	0	**6**[i]	11	99

[i] Patient specimens with Specimen IDs 569915, 579796, 579821, 569790, 570955 and 577368 were found to be positive despite a near threshold negative result

Discordant sample resolution

Assay	Cutoff Value (ng/mL)	Specimen ID	Quidel Triage TOX DS 94600 Result (POS/NEG)	Drug/Metabolite Detected	GC/MS or LC/MS/MS value (ng/mL)
COC	150	569915[i]	COC False Positive	Benzoylecgonine	113
COC	150	579796[i]	False Positive	Benzoylecgonine	126
COC	150	579821[i]	False Positive	Benzoylecgonine	128
COC	150	569790[i]	False Positive	Benzoylecgonine	129
COC	150	570955[i]	False Positive	Benzoylecgonine	144
COC	150	577368[i]	False Positive	Benzoylecgonine	144

EDDP (Cutoff = 100 ng/mL)					
		Reference Method Result by GC/MS or LC-MS/MS Value			
Drug	**Quidel Triage TOX Drug Screen, 94600**	**Negative (<50% of threshold)**	**Near Threshold Negative (within 50% below threshold)**	**Near Threshold Positive (within 50% above threshold)**	**Positive (>150% of threshold)**
EDDP	Negative	99	9	**2[j]**	0
	Positive	0	**1[k]**	10	98

[j] Patient specimen with Specimen ID 572444 was found to be positive despite a near threshold negative result

[k] Patient specimens with Specimen IDs 572432 and 572426 were found to be negative despite a near threshold positive result

Discordant sample resolution

Assay	Cutoff Value (ng/mL)	Specimen ID	Quidel Triage TOX DS 94600 Result (POS/NEG)	Drug/Metabolite Detected	GC/MS or LC/MS/MS value (ng/mL)
EDDP	100	572444[j]	False Positive	EDDP	76
EDDP	100	572432[k]	False Negative	EDDP	100
EDDP	100	572426[k]	False Negative	EDDP	110

OPI (Cutoff = 300 ng/mL)					
		Reference Method Result by GC/MS or LC-MS/MS Value			
Drug	**Quidel Triage TOX Drug Screen, 94600**	**Negative (<50% of threshold)**	**Near Threshold Negative (within 50% below threshold)**	**Near Threshold Positive (within 50% above threshold)**	**Positive (>150% of threshold)**
OPI	Negative	99	2	0	**1[m]**

	Positive	0	**8**[l]	11	98

[l] Patient specimens with Specimen IDs 572508, 570415, 586327, 582860, 572488, 586330, 582932 and 586359 were found to be positive despite a near threshold negative result

[m] Patient specimen with Specimen ID 572644 was found to be negative despite a high positive result

Discordant sample resolution

Assay	Cutoff Value (ng/mL)	Specimen ID	Quidel Triage TOX DS 94600 Result (POS/NEG)	Drug/Metabolite Detected	GC/MS or LC/MS/MS value (ng/mL)
OPI	300	572508[l]	False Positive	Hydrocodone	353
OPI	300	570415[l]	False Positive	Oxycodone	24859
				Oxymorphone	217
OPI	300	586327[l]	False Positive	Morphine	228
OPI	300	582860[l]	False Positive	Hydrocodone	469
OPI	300	572488[l]	False Positive	Morphine	239
OPI	300	586330[l]	False Positive	Morphine	260
OPI	300	582932[l]	False Positive	Hydrocodone	488
				Hydromorphone	67
OPI	300	586329[l]	False Positive	Morphine	285
OPI	300	572644[m]	False Negative	Morphine	2097
				Oxycodone	2674
				Oxymorphone	137

[m] The initial reference testing laboratory result for Specimen ID 572644 was positive for opiates while the Quidel Triage TOX Drug Screen, 94600 OPI assay result was negative. Specimen ID 572644 was sent to a second reference testing laboratory and was confirmed to be negative for opiates. The second result is concordant with the Quidel Triage TOX Drug Screen, 94600 OPI assay result.

THC (Cutoff = 50 ng/mL)					
		Reference Method Result by GC/MS or LC-MS/MS Value			
Drug	**Quidel Triage TOX Drug Screen, 94600**	**Negative (<50% of threshold)**	**Near Threshold Negative (within 50% below threshold)**	**Near Threshold Positive (within 50% above threshold)**	**Positive (>150% of threshold)**
THC	Negative	99	10	**3**[o]	0
	Positive	0	**1**[n]	8	99

[n] Patient specimen with Specimen ID 570021 was found to be positive despite a near threshold negative result

[o] Patient specimens with Specimen IDs 570366, 575089, and 569400 were found to be negative despite a near threshold positive result

Discordant sample resolution

Assay	Cutoff Value (ng/mL)	Specimen ID	Quidel Triage TOX DS 94600 Result (POS/NEG)	Drug/Metabolite Detected	GC/MS or LC/MS/MS value (ng/mL)
THC	50	570021[n]	False Positive	11-nor-9-Carboxy-delta 9-THC	31
THC	50	570366[o]	False Negative	11-nor-9-Carboxy-delta 9-THC	51
THC	50	575089[o]	False Negative	11-nor-9-Carboxy-delta 9-THC	56
THC	50	569400[o]	False Negative	11-nor-9-Carboxy-delta 9-THC	63

TCA (Cutoff = 1,000 ng/mL)					
		Reference Method Result by GC/MS or LC-MS/MS Value			
Drug	**Quidel Triage TOX Drug Screen, 94600**	**Negative (<50% of threshold)**	**Near Threshold Negative (within 50% below threshold)**	**Near Threshold Positive (within 50% above threshold)**	**Positive (>150% of threshold)**
TCA	Negative	98	1	0	**1[r]**
	Positive	**1[p]**	**10[q]**	11	95

[p] Patient specimen with Specimen ID 586712 was found to be positive despite a high negative result
[q] Patient specimens with Specimen IDs 586353, 585878, 582936, 572581, 585866, 586232, 585830, 585879, 582925, and 585874 were found to be positive despite a near threshold negative result
[r] Patient specimen with Specimen ID 586694 was found to be negative despite a high positive result

Discordant sample resolution

Assay	Cutoff Value (ng/mL)	Specimen ID	Quidel Triage TOX DS 94600 Result (POS/NEG)	Drug/Metabolite Detected	GC/MS or LC/MS/MS value (ng/mL)
TCA	1,000	586712[p]	False Positive	Desipramine	0
TCA	1,000	586353[q]	False Positive	Desipramine	637
TCA	1,000	585878[q]	False Positive	Desipramine	639
TCA	1,000	582936[q]	False Positive	Amitriptyline	385
				Nortriptyline	160
TCA	1,000	572581[q]	False Positive	Amitriptyline	149
				Nortriptyline	512
TCA	1,000	585866[q]	False Positive	Desipramine	680
TCA	1,000	586232[q]	False Positive	Desipramine	727
TCA	1,000	585830[q]	False Positive	Desipramine	730

Assay	Cutoff Value (ng/mL)	Specimen ID	Quidel Triage TOX DS 94600 Result (POS/NEG)	Drug/Metabolite Detected	GC/MS or LC/MS/MS value (ng/mL)
TCA	1,000	585879[q]	False Positive	Desipramine	758
TCA	1,000	582925[q]	False Positive	Amitriptyline	162
				Nortriptyline	599
TCA	1,000	585874[q]	False Positive	Desipramine	608
				Doxepin	238
TCA	1,000	586694[r]	False Negative	Desipramine	1646

[p] A data entry error occurred with Specimen ID 586712. This patient specimen was positive for TCA when tested on the Quidel Triage TOX Drug Screen, 94600 and reconfirmed as a near cut-off negative at a secondary reference testing laboratory with value of 864 ng/mL desipramine (within 10.8% of the assay threshold).

[r] Specimen ID 586694 was confirmed to have a pH value of 9.4. A pH value at this level is above the upper limit of the expected range for normal human urine8 and above the upper limit evaluated for performance on the Quidel Triage TOX Drug Screen, 94600. The Quidel Triage TOX Drug Screen, 94600 has been validated with specimens that have a pH range of 4.0 – 9.0, and no excessive interference was observed for each of the assays. In the case of the TCA assay, there was evidence that increasing urine pH levels at the top of the validated range could have an impact on positive control sample results as the assay cutoff of 1,000 ng/mL was approached. Specimens tested outside of the validated pH range may yield inaccurate results.

b. Method comparison with reference method:

Not applicable. These devices are for use with human urine samples only.

3. Clinical studies:

a. Clinical sensitivity:

Not applicable.

b. Clinical specificity:

Not applicable.

c. Other clinical supportive data (when a. and b. are not applicable):

Not applicable.

4. Clinical cut-off:

Not applicable.

5. Expected values/Reference range:

Not applicable.

1.14. Conclusion:

These studies demonstrated the substantial equivalence of the Quidel Triage TOX Drug Screen, 94600 to the GenPrime Drugs of Abuse (DOA) Reader System (K130082), Immunalysis Barbiturates Urine Enzyme Immunoassay (K161714), DRI Benzodiazepine Assay (K173963), Immunalysis EDDP Specific Urine Enzyme Immunoassay (K151395), Triage® TOX Drug Screen (K043242), and Triage Meter (K973547). Such studies are a critical element in establishing the fundamental safety and effectiveness of the product and its appropriateness for commercial distribution.