510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY AND INSTRUMENT COMBINATION TEMPLATE

A. 510(k) Number:

k182719

B. Purpose for Submission:

New Device

C. Measurand:

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

D. Type of Test:

Qualitative, lateral flow immunofluorence

E. Applicant:

Quidel Cardiovascular Inc.

F. Proprietary and Established Names:

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

G. Regulatory Information:

Product Code	Classification	Regulatory Section	Panel
DKZ	Class II	21 CFR 862.3100, Amphetamine test system	Toxicology (91)
LAF	Class II	21 CFR 862.3610, Methamphetamine test system	Toxicology (91)
DIS	Class II	21 CFR 862.3150, Barbiturate test system	Toxicology (91)

Product Code	Classification	Regulatory Section	Panel
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 862.3620, 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)
KHO	Class I	21 CFR 862.2560, Fluorometer for clinical use	Chemistry (75)

H. Intended Use:

1. Intended use(s):

   See Indication(s) for use below.

2. Indication(s) for use:

   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

Abbreviation	Analyte	Calibrator	Cutoff
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.

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.

3. Special conditions for use statement(s):

   For prescription use only.

4. Special instrument requirements:

   Quidel Triage® MeterPro

I. Device Description:

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 is a competitive-based lateral flow fluorescence immunoassay and contains murine monoclonal antibody conjugates (depending on the test analyte) and drug conjugates labeled with a fluorescent dye or immobilized on the solid phase and stabilizers.

The Quidel Triage® TOX Drug Screen, 94600 is inserted into and read by the Quidel Triage® MeterPro. Threshold concentrations are factory calibrated and are used to determine a negative result or a presumptive positive result for the presence of the major urinary metabolites of the following substances in human urine: amphetamine (AMP), methamphetamine (mAMP), barbiturates (BAR), benzodiazepines (BZO), cocaine (COC), methadone metabolite, (2- ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine), (EDDP), opiates (OPI), cannabinoid (THC), and tricyclic antidepressants (TCA).

The Quidel Triage TOX Drug Screen, 94600 Test is provided as a kit that contains 25 test devices, 25 transfer pipettes, one reagent CODE CHIP Module and 2 printer paper rolls. The test device is individually wrapped for one time use only.

Quidel Triage® MeterPro, and Quidel Triage TOX Drug Screen, 94600 Control 1 and 2 are needed but not provided with the kit.

The Quidel Triage® MeterPro is a portable fluorescence instrument. It uses a laser diode as the excitation light source and a silicon photodiode as the light detector for the reaction. 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, and this fluorescence is captured by the light detector. The amount of fluorescence produced directly correlates with analyte concentrations in an analyte-specific manner. Results are displayed on a liquid crystal display or hard copies can be printed via the internal printer.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   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(s):

   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	Quidel Triage® TOX Drug Screen, 94600 (Proposed Device)	GenPrime Drugs of Abuse (DOA) Reader System (K130082) (Predicate Device)
Intended Use	For the qualitative determination of drugs of abuse in human urine.	Same
Intended Population	Prescription use	Same

Similarities		
Item	Quidel Triage® TOX Drug Screen, 94600 (Proposed Device)	GenPrime Drugs of Abuse (DOA) Reader System (K130082) (Predicate Device)
Assay Type	Competitive assay where concentration of drug is inversely related to the signal detected by the instrument.	Same
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	Quidel Triage® TOX Drug Screen, 94600 (Proposed Device)	GenPrime Drugs of Abuse (DOA) Reader System (K130082) (Predicate Device)
Test Device Reader	Quidel Triage® MeterPro	GenPrime DOA Reader
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

Assay: Barbiturates (BAR)

Similarities		
Item	Quidel Triage® TOX Drug Screen, 94600 (Proposed Device)	ImmunalysisBarbiturates Urine Enzyme Immunoassay (K161714) (Predicate Device)
Intended Use	For the qualitative determination of drugs of abuse in human urine.	Same
Specimen Type	Human urine	Same
Storage	2-8°C	Same
Measured Analyte	BAR	Same
Analyte Cutoff (ng/mL)	BAR = 200	Same

Differences		
Item	Quidel Triage® TOX Drug Screen, 94600 (Proposed Device)	ImmunalysisBarbiturates Urine Enzyme Immunoassay (K161714) (Predicate Device)
Antibody Type	Mouse monoclonal antibodies	Recombinant and monoclonal antibodies

Assay: Benzodiazepines (BZO)

Similarities		
Item	Quidel Triage® TOX Drug Screen, 94600 (Proposed Device)	DRI Benzodiazepine Assay (K173963) (Predicate Device)
Intended Use	For the qualitative determination of drugs of abuse in human urine.	Same
Specimen Type	Human urine	Same
Storage	2-8°C	Same
Analyte Cutoff (ng/mL)	BZO = 200	Same

Differences		
Item	Quidel Triage® TOX Drug Screen, 94600 (Proposed Device)	DRI Benzodiazepine Assay (K173963) (Predicate Device)
Antibody Type	Mouse monoclonal antibodies	Polyclonal sheep antibody

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

Similarities		
Item	Quidel Triage® TOX Drug Screen, 94600 (Proposed Device)	Immunalysis EDDP Specific Urine Enzyme Immunoassay (K151395) (Predicate Device)
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	Quidel Triage® TOX Drug Screen, 94600 (Proposed Device)	Immunalysis EDDP Specific Urine Enzyme Immunoassay (K151395) (Predicate Device)
Antibody Type	Mouse monoclonal antibodies	Recombinant fab antibodies

Assay: Tricyclic Antidepressants (TCA)

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

Differences		
Item	Quidel Triage® TOX Drug Screen, 94600 (Proposed Device)	Triage® TOX Drug Screen (K043242) (Predicate Device)
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:

Similarities		
Item	Quidel Triage® MeterPro (Proposed Device)	Triage Meter (K973547) (Predicate Device)
Intended Use	Fluorometer for the measurement of fluorescence in various assay systems.	Same
Device Class	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
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
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.	Same

Differences		
Item	Quidel Triage® MeterPro (Proposed Device)	Triage Meter (K973547) (Predicate Device)
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
Output	If connected, the MeterPro can transmit results to the laboratory or hospital information system.	The Triage Meter does not have capability to transmit results to the laboratory or hospital information system.

K. Standard/Guidance Document Referenced (if applicable):

None referenced.

L. Test Principle:

The Quidel Triage TOX Drug Screen, 94600 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 of 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 tests use monoclonal antibodies against 9 targeted drugs or metabolites in the patient urine sample. The tests utilize a competitive immunoassay format in which the fluorescence results are inversely proportional to the analyte concentration. If the assay spot concentration is less than the assay-specific threshold then the result will be reported as positive. If the assay spot concentration is equal to or greater than the test-specific threshold then the result will be reported as negative.

The tests contain positive on-board test device controls. Before calculating whether the test is positive or negative for each assay spot, the algorithm checks to ensure that the acceptance criteria for the on-board test device controls have been met. If any have not been met, the assay result is reported as invalid.

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 at a specified time after the addition of specimen. 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.

M. Performance Characteristics (if/when applicable):

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 representative point of care (POC) sites using three device lots and 45 meters. Three operators conducted the testing at each POC site. Each operator was assigned one test device lot and five Triage MeterPro instruments to conduct the testing. Each operator tested ten samples each day of testing. The ten samples were run in duplicate two times per day for twenty days at each clinical site. Each device was read on one Triage MeterPro. There were approximately 720 results (N=4x20x9) 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.

Actual Drug Concentration (ng/mL)	Target Drug Levels (% of Cutoff)	Number of Replicates (N)	Number of Negative Results	Number of Positive Results
AMP (500 ng/mL)				
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
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
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 (controls, calibrators, or methods):

Quidel Triage TOX Drug Screen, 94600
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 (20°C to 24°C) and within four days when stored refrigerated (2°C to 8°C). No more than a single freeze/thaw cycle is recommended.

d. Detection limit:

See assay cutoff characterization data in Section M.1.a, above, and M.1.f., below, for device performance around the claimed cutoff concentrations.

e. Analytical specificity:

Analytical Specificity
To test cross-reactivity, drug metabolites and other compounds that may be present in human urine samples were tested using nine 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

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

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
Benzodioxazolybutanamine (BDB)	25,000	2.0

mAMP (Cutoff = 500 ng/mL)	Results Positive at (ng/mL)	% Cross-Reactivity
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
Isometheptine	50,000	1.0
Mephentermine	25,000	2.0
p-Methoxyamphetamine (PMA)	>200,000	0.0
p-Methoxymethamphetamine (PMMA)	2,200	22.7
Propylamphetamine	>200,000	0.0
p-Hydroxymethamphetamine	1,000	50.0

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
Phenallymal	400	50.0
Pentobarbital	500	40.0

BAR (Cutoff = 200 ng/mL)	Results Positive at (ng/mL)	% Cross-Reactivity
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
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
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

BZO (Cutoff = 200 ng/mL)	Results Positive at (ng/mL)	% Cross-Reactivity
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
Hydroxybenzoylecgonine, m-	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-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
l-iso-methadone	>100,000	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

OPI (Cutoff = 300 ng/mL)	Results Positive at (ng/mL)	% Cross-Reactivity
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
Nor-Buprenorphine	>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-nor-9 carboxy-Δ^9-THC*	50	100.0
11-nor- Δ^8-THC-COOH	100	50
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
Tetrahydocannabinol	3,000	1.7
(+/-) 11-hydroxy- Δ^9-THC	1,500	3.3

TCA (Cutoff = 1,000 ng/mL)	Results Positive at (ng/mL)	% Cross-Reactivity
Amitriptyline	600	166.7
Amitryptyline metabolite	300	333.3
Chlorpromazine	>400,000	0.0
Chlorprothixene	40,000	2.5

TCA (Cutoff = 1,000 ng/mL)	Results Positive at (ng/mL)	% Cross-Reactivity
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 and Interference Testing of Non-Structurally Related Pharmaceutical Compounds

Potential interference from pharmaceutical compounds were tested by spiking the potentially interfering pharmaceutical compound 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 concentration 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 in the table below, along with the assay in which it interfered.

Acetaminophen	Dronabinol (1 µg/mL; THC)	Olanzapine
Acetophenetidin	Droperidol	Oxalic Acid
Acetopromazine (maleate salt)	Duloxetine	Oxaprozin
Amantadine	Efavirenz	Pantoprazole
Amoxicillin	L-Epinephrine	Papaverine
Ampicillin	Fenfluramine (2 µg/mL; AMP and mAMP)	Pentazocine
Aspirin (salicyluric	Flunitrazepam (0.2	Pericyazine

acid)	µg/mL; BZO)	
Atenolol	Fluoxetine	Phenelzine
Atorvastatin	Gamma-Hydroxybutyrate	Phenethylamine (2-Phenylethyamine) (6 µg/mL; AMP)
Benzocaine	Glutethimide (10 µg/mL; BAR)	Phenmetrazine (37.5 µg/mL; TCA)
Benzydamine	Haloperidol	Phentermine
Buprenorphine	Ibuprofen	Phenylephrine
Benztropine Methane	Ketamine	Phenylhydantoin, d/1-5(p-hydroxyphenyl)-5-
Bupropion	Ketorolac Tromethamine	Phenylpropanolamine
Butyrophenone	Labetalol	Promethazine
Carbamazepine	Levofloxacin	Propranolol, d/l
Chlorpheniramine	Levorphanol (18.75 µg/mL; OPI)	d-Pseudoephedrine (50 µg/mL; THC)
Chlorpromazine	Meperidine	Quetiapine
Cimetidine	Mesoridazine Besylate	Quinacrine (50 µg/mL; THC)
Citalopram	Methaqualone	Quinine
Clomipramine (5 µg/mL; TCA)	Methoxyphenamine	Ranitidine
Clonidine	Methylphenidate	Rifampin
Cotinine [l-Cotinine]	Nalbuphine	Ritodrine
Cyproheptadine	Naloxone	Selegiline
Dexamphetamine (0.4 µg/mL; AMP)	Naltrexone	Sertraline
Dextromethorphan	Naproxen [(S)-6-Methoxy-α-methyl-2 Naphthaleneacetic acid]	Thioridazine
Dextrorphan Tartrate	N-desmethylvenlafaxine	Tramadol
Dimethylamine	Niacinamide	Tranylcypromine
Diphenhydramine	Nicotine	Trimethobenzamide
Dopamine	Norpseudoephedrine (25 µg/mL; AMP)	Tyramine (25 µg/mL; AMP)
Dothiepin (0.7 µg/mL; TCA)	O-desmethylvenlafaxine	Verapamil
Doxylamine Succinate	d,l-Octopamine	Zolpidem
Doxepin (0.65 µg/mL; TCA)	Ofloxacin	Benzphetamine
Clobenzorex	Fenproporex	Meprobamate
Nalmefene		

Interference from Exogenous Compounds

Potential interference from exogenous compounds were tested by spiking the potentially interfering compound 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
Scopalamine	62.5 µg/mL

Interference from Endogenous Compounds

Potential interference from endogenous compounds were tested by spiking the potentially interfering compound 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. Within the pH range of 4.0 to 9.0 acceptable results were observed with the samples tested. However, a low level of interference was noted with the TCA assay as the pH increased which could impact results which are above the threshold of 1,000 ng/mL. Specimens tested outside of the validated pH range of 4.0 to 9.0 may yield inaccurate results.

The sponsor has included the following statement under 'Warnings and Precautions' section of the labeling:
"*The Quidel Triage TOX Drug Screen, 94600 has been validated with specimens that have a pH range of 4.0 – 9.0 acceptable results were observed with the samples tested. However, a low level of interference was noted with the TCA assay as the pH increased which could impact results which are above the threshold of 1,000 ng/mL. 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). Based on the study results, the Quidel Triage TOX Drug Screen, 94600 is 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 (R.H.) ranging from ≤ 10 %R.H. to 85 %RH. The Quidel Triage TOX Drug Screen, 94600 is validated for an operating relative humidity (R.H.) range from 10 %R.H. to 85 %R.H. for all analyte assays.

The sponsor has included the following statement in the devicelabeling under the 'Warnings and Precautions' section:
"*Optimal results will be achieved by performing testing at temperatures between 18°C to 28°C (64°F to 82°F) and between a relative humidity (RH) range of 10 %RH to 85 %RH. Specimens tested outside of the validated temperature range may yield inaccurate results particularly for the cocaine, methamphetamines and opiates 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

over four days. Each test sample was run on 105 test devices per device lot for a total of 315 results per sample. For each test device lot, 40 unique meters were used to complete all test measurements. Combined results from three test device lots for each drug test is summarized below.

Amphetamine (AMP) 500 ng/mL		
Concentration (ng/mL)	% of cutoff	Results #Neg/#Pos
Negative Control	0%	315/0
0	0%	315/0
126	25%	315/0
281	50%	315/0
395	75%	313/2
522	100%	49/266
650	125%	1/314
760	150%	0/315
884	175%	0/315
991	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
130	25%	315/0
250	50%	315/0
366	75%	312/3
529	100%	127/188
652	125%	11/304
742	150%	2/313
872	175%	0/315
961	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
53	25%	315/0
108	50%	315/0
156	75%	309/6
192	100%	78/237
233	125%	1/314
306	150%	1/314
355	175%	0/315
406	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
58	25%	315/0
107	50%	315/0
166	75%	296/19
219	100%	242/73
259	125%	3/312
306	150%	0/315
378	175%	0/315
399	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
41	25%	315/0
76	50%	315/0

Cocaine (COC) 150 ng/mL		
119	75%	279/36
157	100%	10/305
185	125%	1/314
218	150%	0/315
267	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
29	25%	315/0
52	50%	315/0
85	75%	315/0
111	100%	115/200
136	125%	11/304
143	150%	0/315
174	175%	0/315
204	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
87	25%	315/0
165	50%	315/0
231	75%	315/0
344	100%	132/183
426	125%	1/314
480	150%	0/315
548	175%	0/315
589	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	25%	315/0
26	50%	315/0
39	75%	295/20
54	100%	20/295
65	125%	0/315
78	150%	0/315
91	175%	0/315
103	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
236	25%	315/0
498	50%	315/0
741	75%	300/15
996	100%	161/154
1,395	125%	5/310
1,577	150%	1/314
1,716	175%	0/315
2,195	200%	0/315

2. Comparison studies:

   a. Method comparison with predicate device:

   A method comparison study was conducted using unaltered urine specimens tested on the Quidel Triage TOX Drug Screen, 94600 and compared to results from a chemically-specific quantitative comparator method. Results are summarized below.

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

Values

		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 (500)	Negative	99	11	2[a]	2[b]
	Positive	0	0	8	98
mAMP (500)	Negative	99	5	5[d]	7[e]
	Positive	0	5[c]	6	91
BAR (200)	Negative	99	3	0	0
	Positive	0	8[f]	11	97
BZO (200)	Negative	99	1	1[h]	0
	Positive	0	10[g]	10	99
COC (150)	Negative	99	5	0	0
	Positive	0	6[i]	11	99
EDDP (100)	Negative	99	9	2[j]	0
	Positive	0	1[k]	10	98
OPI (300)	Negative	99	2	0	1[m]
	Positive	0	8[l]	11	98
THC (50)	Negative	99	10	3[o]	0
	Positive	0	1[n]	8	99
TCA (1,000)	Negative	98	1	0	1[r]
	Positive	1[p]	10[q]	11	95

Discordant Results - 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

[a] These two patient specimens were read negative despite a near threshold positive results by the reference method.

[b] These two patient specimens were read negative despite a high positive result. 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 by the reference method. 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

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

[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. 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).

mAMP 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

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

[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.

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

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)
				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

[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.

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

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

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

[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.

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

[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. 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.

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-	63

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)
				Carboxy-delta 9-THC	

[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.

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
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] Patient specimen with Specimen ID 586712 was found to be positive despite a high negative result. 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).

[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. 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 urine 8 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 acceptable results were observed with the samples tested. However, a low level of interference was noted with the TCA assay as the pH increased which could impact results which are above the threshold of 1,000 ng/mL. Specimens tested outside of the validated pH range may yield inaccurate results.

b. Matrix comparison:

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.

N. Instrument Name:

Quidel Triage® MeterPro

O. System Descriptions:

1. Modes of Operation:

Does the applicant's device contain the ability to transmit data to a computer, webserver, or mobile device?

Yes ____X____ or No _____

Does the applicant's device transmit data to a computer, webserver, or mobile device

using wireless transmission?

Yes _____ or No ___X_____

2. Software:

   FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types:

   Yes ___X_____ or No _____

3. Specimen Identification:

   There is no sample identification function with this device. Samples are applied directly to the test device.

4. Specimen Sampling and Handling:

   This device is intended to be used with urine samples. The labeling provides instructions for storage of samples.

5. Calibration:

   Lot Calibration of the meter is performed using Reagent CODE CHIP Module which is specific to each lot of the test device.

6. Quality Control:

   For the meter quality control, the device operator installs the QC Device CODE CHIP Module in the meter. After installation, the operator runs the QC Device every day prior to running the external quality control samples and patient samples to assess the functioning of the meter lasers etc.

   The QC Sample CODE CHIP module is lot specific. The operator installs the QC Sample CODE CHIP module in the meter prior to testing of the external QC samples (Control 1 and 2).

   The sponsor specifies in the labeling the quality control products that must be used with the device systems.

P. Other Supportive Instrument Performance Characteristics Data Not Covered In The "Performance Characteristics" Section above:

Not applicable.

Q. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Parts 801 and 809, as applicable.

R. Conclusion:

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