QUIDEL

Triage®

TOX DRUG SCREEN 94600

Rapid qualitative simultaneous detection of drug and/or urinary metabolites of up to 9 assays.

For *in vitro* diagnostic use. Rx ONLY

A symbols glossary can be found at quidel.com/glossary.

INTENDED 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 drug 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	500ng/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-Δ^9-THC	50 ng/mL
TCA	Tricyclic Antidepressants	Desipramine	1000 ng/mL

This test provides only a preliminary result. Clinical consideration and professional judgment must be applied to any drug of abuse 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.

SUMMARY AND EXPLANATION OF THE TEST

Drug abuse in the United States continues to be an increasingly significant social and economic problem. Opiates, cocaine, THC, amphetamines are recognized by the Substance Abuse and Mental Health Services Administration (SAMHSA) as the most frequently abused illicit drugs. Benzodiazepines, tricyclic antidepressants, barbiturates and opiate compounds are among a group of prescription drugs that also are frequently abused. The opiate class of compounds that may produce a positive result include illicit opiates as well as cough medications containing codeine.

Urine-specific screening tests for drugs of abuse range from simple immunoassay tests to complex analytical procedures. The speed and sensitivity of immunoassays have made them the most accepted method for screening urine for the presence of drugs.

The Quidel Triage TOX Drug Screen, 94600 uses distinct immunoassays for the simultaneous detection of drug and/or the urinary metabolites of up to 9 different drug classes. The use of monoclonal antibodies that are specific for the metabolites of the 9 drug classes ensures a high degree of sensitivity and specificity.

Amphetamines (AMP) and **Methamphetamines (mAMP)** are powerful central nervous system stimulants belonging to the class of phenethylamine compounds. They have therapeutic applications as well as a high potential for abuse and illicit use. The Quidel Triage TOX Drug Screen, 94600 has separate assays for the detection of amphetamine and methamphetamine.

Barbiturates (BAR) are a class of structurally related compounds derived from barbituric acid. They are central nervous system depressants used therapeutically for their sedative, anesthetic and anticonvulsant properties. The abuse and misuse of barbiturates can lead to severe respiratory depression, coma and death.

Benzodiazepines (BZO) are a class of structurally related compounds that are central nervous system depressants. They are commonly prescribed as anxiolytics, sedative/hypnotics, anticonvulsants and muscle relaxants. They have a high potential for abuse and misuse can lead to tolerance and dependence.

Cocaine (COC) is a potent central nervous system stimulant with a high potential for abuse and dependence. Extracted from the leaves of the South American Coca plant, it is used medically as a local anesthetic. Chronic abuse can lead to severe dysphoria and depression and an overdose can result in death due to hyperthermia and cardiac or respiratory arrest.

EDDP (2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine) is a primary metabolite of methadone in urine. Methadone is a narcotic analgesic used for pain management and opioid cessation/withdrawal treatment. The detection of the metabolite EDDP, is important for assessing and monitoring patient compliance.

Opiates (OPI) are a class of drugs derived from the opium poppy and include heroin, morphine and codeine. Both heroin and codeine metabolize to morphine. They are narcotic analgesics and potent central nervous system depressants. Regular use leads to dependence and overdose can result in death.

Tetrahydrocannabinol (THC) is one of the more psychoactive cannabinoids naturally occurring in the hemp plant (*Cannabis sativa*). Severe cannabis intoxication can cause anxiety, confusion, visual impairment, memory deficit, acute paranoid psychosis and hallucinations.

Tricyclic Antidepressants (TCA) are prescribed for treatment of depressive disorders as well as insomnia, neuropathic pain and smoking cessation. Misuse and abuse can cause respiratory depression, convulsions, severe cardiac conditions and coma.

PRINCIPLES OF THE TEST PROCEDURE

The Quidel Triage TOX Drug Screen, 94600 is a competitive fluorescence immunoassay designed for the qualitative determination of parent drugs and/or drug metabolites in urine specimens.

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 (hereafter referred to as Meter). The Meter is programmed to perform the analysis after the specimen has reacted with the reagents within the Test Device. The analysis is based on the amount of fluorescence the Meter detects within a measurement zone on the Test Device. Under typical conditions, the positive or negative results are displayed on the Meter screen in approximately 15 minutes from the addition of specimen. All results are stored in the Meter memory to display or print when needed. If connected, the Meter can transmit results to the laboratory or hospital information system.

REAGENTS AND MATERIALS PROVIDED

The Test Device contains all the reagents necessary for the qualitative determination of drugs and/or their metabolites in human urine.

The Test Device contains:

- Murine monoclonal antibodies against drug metabolites
- Fluorescently labeled antibodies
- Fluorescently labeled conjugates
- Solid phase
- Stabilizers

Kit Contents

Component	Quantity	Description
	25	Test Devices
	25	Transfer Pipettes
	1	Reagent CODE CHIP™ Module
	2	Printer Paper Rolls

MATERIALS REQUIRED BUT NOT PROVIDED

- Quidel Triage MeterPro, Cat. # 55070 or 55071 – *software version 05.03.046 or greater*
- Quidel Triage TOX Drug Screen, 94600 Control 1, Cat. # 94613
- Quidel Triage TOX Drug Screen, 94600 Control 2, Cat. # 94614

WARNINGS AND PRECAUTIONS

- For *in vitro* diagnostic use.
- For use by healthcare professionals.
- Do not use the kit beyond the expiration date printed on the outside of the box.
- Carefully follow the instructions and procedures described in this insert.
- 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, methamphetamine and opiate assays.
- Keep the Test Device in the sealed pouch until ready for immediate use. Discard after single use.
- The transfer pipette should be used for one patient specimen only. Discard after single use.
- Sample dilution is not recommended.
- The Quidel Triage TOX Drug Screen, 94600 has been validated with specimens that have a 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 may yield inaccurate results.
- The use of non-Quidel Control materials is not recommended.
- Although the Centers for Disease Control (CDC) has stated that "Universal precautions do not apply to feces, nasal secretions, sputum, sweat, tears, urine, and vomitus unless they contain visible blood.", the use of gloves is recommended and is good hygienic practice when handling all samples.
- Proper handling and disposal methods of patient specimens, used Test Devices and used transfer pipettes should be established by the laboratory in accordance with local, state and federal regulations.

STORAGE AND HANDLING REQUIREMENTS

- Store the Test Devices in a refrigerator at 2°C to 8°C (36°F to 46°F).
- Once removed from refrigeration, the pouched Test Device is stable for up to 14 days when stored at 18°C to 28°C (64°F to 82°F), but not beyond the expiration date printed on the pouch. With a soft, felt tip marker, gently write the date and time of removal from the refrigerator on the pouch and cross out the manufacturer expiration date printed on the pouch. Care must be taken to document the time the product is at room temperature. Once equilibrated to 18°C to 28°C (64°F to 82°F), do not return the Test Device to refrigeration.
- Before using refrigerated Test Devices, allow individual foil pouches to reach operating temperature (18°C to 28°C or 64°F to 82°F). This will take a minimum of 15 minutes. If a kit containing multiple Test Devices is removed from refrigeration, allow the kit to reach room temperature before use. This will take a minimum of 60 minutes.
- Do not remove the Test Device from the pouch until prepared for immediate use.

SPECIMEN COLLECTION AND PREPARATION

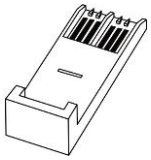
- Freshly voided urine specimens should be collected in a clean, previously unused glass or plastic container. Specimens do not require any special handling or pretreatment.
- Specimens containing a large amount of particulate matter may be clarified by centrifuging or allowing to settle prior to testing.
- Patient specimens are stable for up to 36 hours at room temperature. If the specimen is not tested immediately it should be refrigerated at 2°C to 8°C for a maximum of four days. If longer storage is required, specimens may be stored frozen at –20°C or colder. No more than a single freeze/thaw cycle is recommended.

TEST PROCEDURE

Lot Calibration Using the Reagent CODE CHIP Module

When a new lot of Test Devices is opened, the calibration and expiration data for that lot of Test Devices must be transferred to the Meter before patient testing. Use the Reagent CODE CHIP module supplied with the new lot of Test Devices to transfer the data to the Meter.

Reagent CODE CHIP module



Perform one time for each new lot of Test Devices

1. From the main screen, select **Install New Code Chip**. Press **Enter**.
2. Place the Reagent CODE CHIP module into the lower left front corner of the Meter and follow the prompts on the screen.
3. Remove the Reagent CODE CHIP module from the Meter when data transfer is complete.
4. Place the Reagent CODE CHIP module back into its original container for storage.

Testing Patient Specimens

Procedural Notes

- For each day of patient testing, perform QC Device testing. Refer to the Quality Control Considerations section.
- Frozen and refrigerated specimens must be allowed to reach room temperature and be mixed thoroughly prior to testing.
- If the transfer pipette is misplaced, the addition of patient specimen may be performed with a calibrated precision pipette, adding 250 µL of specimen to the Test Device.

Step 1 – Add Patient Specimen

1. Open the pouch and label the Test Device with the patient identification number.
2. Place the Test Device on a level, horizontal surface.
3. Using the transfer pipette, squeeze the larger (top) bulb completely and insert the tip into the patient specimen.
4. Release the bulb slowly. The transfer pipette barrel should fill completely with some fluid flowing into the smaller (lower) bulb.
   NOTE: Ensure that the pipette is not under filled or over filled. An under filled pipette is one where the barrel is not filled completely with specimen and there is no specimen in the lower bulb. An over filled pipette is one where there is some specimen in the top bulb. Ideally the lower bulb should contain a small amount of specimen (less than one quarter the volume of the lower bulb).
5. Place the tip of the transfer pipette into the sample port of the Test Device and squeeze the larger bulb completely. The entire volume of fluid in the transfer pipette barrel must flow into the sample port. The specimen in the smaller (lower) bulb will not be expelled.
   NOTE: Too much specimen has been added to the device if the specimen has migrated outside of the sample port and on to the label.
6. Remove the transfer pipette tip from the sample port and then release the larger (top) bulb.
7. Discard the transfer pipette.
8. Allow specimen to absorb completely before moving the Test Device.

Step 2 Run – Test

1. From the main screen, select **Run Test** and press **Enter.**
2. Select **Patient Sample** and press **Enter.**
3. Enter the patient identification number and press **Enter.**
4. Confirm that the number was entered correctly by selecting **Confirm Patient ID** and pressing **Enter**. If the number was not entered correctly, select **Correct Patient ID**, press **Enter** and repeat the previous step.
5. Holding the Test Device by the edges, insert the Test Device into the Meter and press **Enter**. The results will be displayed when the analysis is complete.
   NOTE: The Test Device must be inserted into the Meter within 30 minutes from the time the patient specimen was added. A delay longer than 30 minutes may cause the results to be invalid and blocked out on the printout.

Step 3 – Read the Results

1. Results may be printed by pressing the **Print** button.
2. Discard the Test Device after release from the Meter.
3. A blocked out result indicates the result was invalid and the test should be repeated.

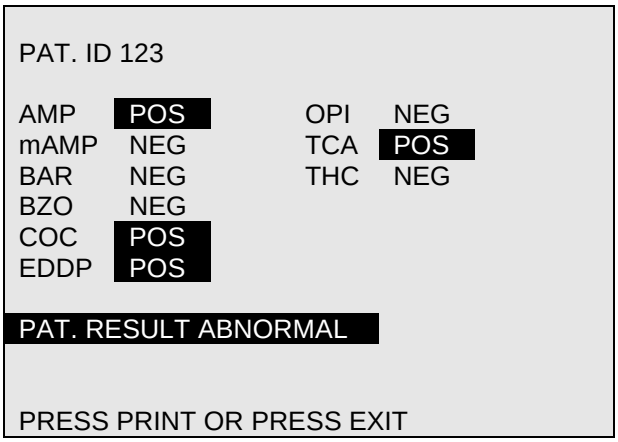
RESULTS

The following threshold concentrations are established for the drug assays:

Amphetamines	**AMP**	500 ng/mL
Methamphetamines	**mAMP**	500 ng/mL
Barbiturates	**BAR**	200 ng/mL
Benzodiazepines	**BZO**	200 ng/mL
Cocaine	**COC**	150 ng/mL
Methadone Metabolite	**EDDP**	100 ng/mL
Opiates	**OPI**	300 ng/mL
Cannabinoids	**THC**	50 ng/mL
Tricyclic Antidepressants	**TCA**	1000 ng/mL

These threshold concentrations are used to separate a negative result from a presumptive positive result. Results are displayed in the following manner:

Example



The Meter displays the results as either “POS” if the result is at or above the threshold or “NEG” if the result is below the threshold. The operator has the option to print the results.

For additional information refer to the Quidel Triage MeterPro User Manual.

A specimen may contain drug and/or drug metabolites at concentrations that do not exceed the threshold concentrations that would otherwise classify the test result as positive. In order to obtain a confirmed analytical result, a more specific alternate chemical method is needed. GC/MS, LC-MS/MS, and HPLC are the common confirmatory methods. Refer to the Performance Characteristics section for additional information.

QUALITY CONTROL CONSIDERATIONS

CLIA Quality Control Considerations

Every Quidel Triage TOX Drug Screen, 94600 Test Device is a qualitative test device that includes positive controls that are run automatically with every patient specimen, external liquid control solution, or proficiency testing sample. If the automatic check of these built-in controls shows that the control value results are within the limits set during manufacturing, the Meter will report a result for the specimen or sample being tested. If the automatic check of these built-in controls shows that the control value results are not within the limits set during manufacturing, a test result will not be reported. Instead, the Meter will display a warning or error message that is described in the Quidel Triage MeterPro User Manual.

Good Laboratory Practice suggests that external controls should be tested with each new lot or shipment of test materials, or every 30 days, and as otherwise required by your laboratory's standard quality control procedures. Controls should be tested in the same manner as if testing patient specimens. When running patient specimens or external controls, if an analyte fails for any reason (built-in control failure or an external control out of range) no patient results will be reported.

Users should follow government guidelines (for example, Federal, State or Local) and/or accreditation requirements for quality control.

Performing Quidel Triage System Quality Control – QC Device

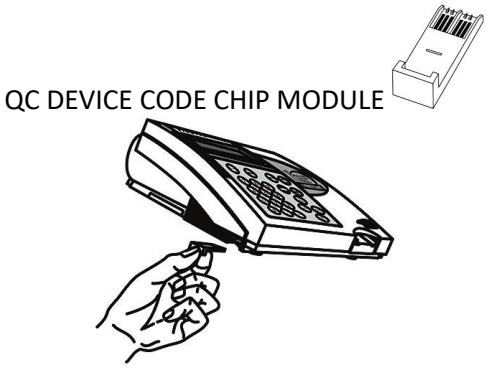
Use the QC Device to ensure proper function of the Meter. Perform QC Device testing for the following conditions:

- Upon initial setup of the Meter.
- Each day of patient testing.
- When the Meter has been transported or moved.
- Whenever there is uncertainty about the performance of the Meter.
- Whenever required by your laboratory's quality control requirements.

Do not discard the Quidel Triage QC Device and associated CODE CHIP module. Store them in the QC Device box.

Refer to the Quidel Triage MeterPro User Manual for complete instructions on use of the QC Device.

1. The first time a new QC Device is run in the Meter, install the QC Device CODE CHIP module. The QC Device CODE CHIP module data is stored in the Meter memory. The QC Device CODE CHIP module does not need to be reinstalled after the first time.



   a. From the main screen, select **Install New Code Chip** and press **Enter**.
   b. Place the QC Device CODE CHIP module into the lower left front corner of the Meter. Follow the prompts on the screen.
   c. Remove the QC Device CODE CHIP module from the Meter when data transfer is complete.
   d. Place the QC Device CODE CHIP module back into the QC Device Box for storage.

2. From the main screen, select **Run Test** and press **Enter.**
3. If User ID is enabled, enter your User ID number and press **Enter**.
4. Select **QC Device** and press **Enter**.
5. Insert **QC Device** into the Meter and press **Enter**.
6. A Pass or Fail result will be displayed when complete. Each parameter should pass before patient testing is performed.
7. Remove the QC Device from the Meter and place in the QC Device Box. **DO NOT DISCARD THE QC DEVICE.**

NOTE: If the QC Device or external controls do not perform as expected, review the above instructions to see if the test was performed correctly, repeat the test, then contact Quidel or your local Quidel representative (refer to the Assistance section). Refer to the Quidel Triage MeterPro User Manual for a complete description of the quality control system.

LIMITATIONS OF THE TEST PROCEDURE

- Adulterants, such as bleach or other strong oxidizing agents, added to urine specimens may produce erroneous results regardless of the method of analysis. If adulteration is suspected, obtain an additional specimen and re-test using a new Test Device.
- There is a possibility that substances and/or factors may interfere with the test and cause false results. Technical or procedural errors can also contribute to erroneous results.
- A presumptive positive result does not indicate the level of intoxication, nor does it indicate the route of administration.
- Test results must always be evaluated with other data available to the physician.
- The performance of this product has been established for human urine only. Other specimen types have not been evaluated.

PERFORMANCE CHARACTERISTICS

Precision

A multi-center precision study was conducted in the intended use setting by intended users at three (3) distinct professional laboratories using a coded panel of contrived samples. The contrived samples contained each drug or drug metabolite spiked into drug-free urine. The purpose of the precision study was to demonstrate that personnel at the study sites could perform the Quidel Triage TOX Drug Screen, 94600 consistently and correctly. There were three (3) different operators at each study site. A total of fifteen (15) Quidel Triage MeterPro instruments were used at each site. Each operator performed the testing on twenty (20) different days using three (3) unique Test Device lots. A summary of the results is provided in the table below.

Sample Concentration (ng/mL)	% of Cutoff	n	# Neg	# Pos
AMP (500 ng/mL)				
0	0	720	720	0
250	–50	716	712	4
750	+50	720	0	720
1,000	+100	736	0	736
mAMP (500 ng/mL)				
0	0	736	736	0
250	–50	720	720	0
750	+50	722	2	720
1,000	+100	704	0	704
BAR (200 ng/mL)				
0	0	704	704	0
100	–50	720	719	1
300	+50	719	0	719
400	+100	720	0	720
BZO (200 ng/mL)				
0	0	720	720	0
100	–50	736	735	1
300	+50	720	0	720
400	+100	722	0	722
COC (150 ng/mL)				
0	0	716	716	0
75	–50	719	719	0
225	+50	736	0	736
300	+100	720	0	720
EDDP (100 ng/mL)				
0	0	722	722	0
50	–50	704	702	2
150	+50	716	0	716
200	+100	719	0	719
OPI (300 ng/mL)				
0	0	720	720	0
150	–50	722	722	0
450	+50	720	0	720

Sample Concentration (ng/mL)	% of Cutoff	n	# Neg	# Pos
600	+100	716	0	716
THC (50 ng/mL)				
0	0	720	720	0
25	–50	720	717	3
75	+50	704	4	700
100	+100	720	0	720
TCA (1,000 ng/mL)				
0	0	719	719	0
500	–50	720	719	1
1,500	+50	720	1	719
2,000	+100	720	0	720

The observed concordance in this study is > 99% for all analyte concentrations and Test Device lots combined.[1]

[1] Expected product performance for all released, individual Test Device lots shall result in all analytes demonstrating that ≥ 98% concordance falls within the 95% confidence interval.

Specificity

The specificity of each of the 9 assays in the Quidel Triage TOX Drug Screen, 94600 has been tested with over 100 drugs and closely related compounds. Representative data are listed below, expressed as the concentration that produced a positive result during development studies and the calculated percent cross-reactivity. 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
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
Metharbital	1,000	20.0
p-Hydroxyphenobarbital	700	28.6
Phenallymal	400	50.0
Pentobarbital	500	40.0
Phenobarbital	230	87.0
Secobarbital	700	28.6
Talbutal	200	100.0
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
Alprazolam glucuronide-OH	1500	13.3
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	80.0
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

Pharmaceuticals

The following compounds were found to be negative in all tests and did not cross-react when tested at concentrations of 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.

5-(4-Hydroxyphenyl)-5-phenylhydantoin	Doxepin (0.65 µg/mL; TCA)	*d,l*-Octopamine
Acetaminophen	Dronabinol (1 µg/mL; THC)	Ofloxacin
Acetophenetidin	Droperidol	Olanzapine
Acetopromazine (maleate salt)	Duloxetine	Oxalic Acid
Amantadine	Efavirenz	Oxaprozin
Amoxicillin	L-Epinephrine	Pantoprazole
Ampicillin	Fenfluramine (2 µg/mL; AMP and mAMP)	Papaverine
Aspirin (acetylsalicylic acid)	Fenproporex	Pentazocine
Atenolol	Flunitrazepam (0.2 µg/mL; BZO)	Pericyazine
Atorvastatin	Fluoxetine	Phenelzine
Benzocaine	Gamma-Hydroxybutyrate	Phenethylamine (2-Phenylethylamine) (6 µg/mL; AMP)
Benzphetamine	Glutethimide (10 µg/mL; BAR)	Phenmetrazine (37.5 µg/mL; TCA)
Benzydamine	Haloperidol	Phentermine
Buprenorphine	Ibuprofen	Phenylephrine
Benztropine Mesylate	Ketamine	Phenylpropanolamine
Bupropion	Ketorolac Tromethamine	Promethazine
Butyrophenone	Labetalol	*d/l* -Propranolol
Carbamazepine	Levofloxacin	*d*-Pseudoephedrine (50 µg/mL; THC)
Chlorpheniramine	Levorphanol (12.5 µg/mL; OPI)	Quetiapine
Chlorpromazine	Meperidine	Quinacrine (50 µg/mL; THC)
Cimetidine	Meprobamate	Quinine
Citalopram	Mesoridazine Besylate	Ranitidine
Clobenzorex	Methaqualone	Rifampin
Clomipramine (5 µg/mL; TCA)	Methoxyphenamine	Ritodrine
Clonidine	Methylphenidate	Selegiline
Cotinine [l-Cotinine]	Nalbuphine	Sertraline
Cyproheptadine	Nalmefene	Thioridazine
Dexamphetamine (0.4 µg/mL; AMP)	Naloxone	Tramadol
Dextromethorphan	Naltrexone	Tranylcypromine
Dextrorphan Tartrate	Naproxen [(S)-6-Methoxy-α-methyl-2 Naphthaleneacetic acid]	Trimethobenzamide
Dimethylamine	N-desmethylvenlafaxine	Tyramine (25 µg/mL; AMP)

Interference

Potential interfering substances were evaluated by adding the substance to human urine spiked with drug 50% above and 50% below the threshold concentration. Each specimen was evaluated on the Quidel Triage TOX Drug Screen, 94600. The following substances did not produce false positive or false negative results when tested at the following concentrations:

Test Substance	Test Concentration
Acetaminophen	1 mg/mL
Acetone	5 mg/mL
Acetylsalicylic Acid	1 mg/mL
Ascorbic Acid	15 mg/mL
Bilirubin	2.5 µg/mL
Caffeine	0.125 mg/mL
Creatinine	2.5 mg/mL
Dextrose	20 mg/mL
Ethanol	5 mg/mL
Fluoxetine	0.5 mg/mL
Gamma Globulin	5 mg/mL
Hemoglobin	1.2 mg/mL
Hippuric Acid	10 µg/mL
Human Serum Albumin	5 mg/mL
Ibuprofen	0.75 mg/mL
Ketamine	25 mg/mL
Oxalic Acid	7 mg/mL
Riboflavin	75 µg/mL
Scopolamine	62.5 µg/mL
Sodium Chloride	30 mg/mL
Urea	30 mg/mL

The effect of pH for each analyte was evaluated by testing positive and negative samples over a range of pH levels from 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 may yield inaccurate results.

Specimens having a range of specific gravity values from 1.003 to 1.030 g/mL were evaluated on the Quidel Triage TOX Drug Screen, 94600 Test Devices, and no interference was observed across the specific gravity ranges tested.

Accuracy

The performance of the Quidel Triage TOX Drug Screen, 94600 was evaluated using clinical urine specimens and compared to the reference methods. The results are presented below.

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[c]	False Negative	Amphetamine	1003
AMP	500	572667[c]	False Negative	Amphetamine	1359

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

[c] 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 Ampheta mine (ng/mL)*	Adjudicated Quidel Triage TOX Drug Screen, 94600 AMP Assay Result
				% *d*-Ampheta mine	% *l*-Ampheta mine	*d*-Ampheta mine	*l*-Ampheta mine		
570964[c]	500	1003	False Negative	35.3	64.7	354	649	463	Negative
572667[c]	500	1359	False Negative	28.9	71.1	393	966	554	False Negative

[c] 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).

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[f]**	6	91

[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

[f] Patient specimens with Specimen IDs 578510, 579777, 579705, 579727, and 579806 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)
mAMP	500	578510[f]	False Positive	Methamphetamine	325
mAMP	500	579777[f]	False Positive	Methamphetamine	402
mAMP	500	579705[f]	False Positive	Methamphetamine	445
mAMP	500	579727[f]	False Positive	Methamphetamine	490
mAMP	500	579806[f]	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
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[g]	False Negative	Methamphetamine	984
mAMP	500	586275[g]	False Negative	Methamphetamine	990
mAMP	500	586300[g]	False Negative	Methamphetamine	1028
mAMP	500	579757[e]	False Negative	Methamphetamine	1568

[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

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

[g] 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).

Discordant sample resolution

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[g]	831	500	False Negative	52.3	434.6	Negative
586269[g]	937	500	False Negative	52.8	494.7	Negative
586264[g]	940	500	False Negative	52.9	497.3	Negative
586282[g]	984	500	False Negative	52.2	513.6	False Negative
586275[g]	990	500	False Negative	52.3	517.8	False Negative
586300[g]	1028	500	False Negative	52.8	542.8	False Negative
579757[g]	1568	500	False Negative	19.9	312.0	Negative

[g] 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).

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[h]**	11	97

[h] 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)
BAR	200	582858[h]	False Positive	Phenobarbital	120
BAR	200	575082[h]	False Positive	Phenobarbital	172
BAR	200	575081[h]	False Positive	Butalbital	150
BAR	200	575079[h]	False Positive	Butalbital	151
BAR	200	586932[h]	False Positive	Amobarbital	164
BAR	200	575085[h]	False Positive	Butalbital	165
BAR	200	575084[h]	False Positive	Phenobarbital	210
BAR	200	575095[h]	False Positive	Butalbital	197

[h] 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

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**[i]	0
	Positive	0	**10**[j]	10	99

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

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[j]	False Positive	Alprazolam-OH	79
BZO	200	586234[j]	False Positive	Alprazolam-OH	80
BZO	200	586235[j]	False Positive	Alprazolam-OH	86
BZO	200	582865[j]	False Positive	7-aminoclonazepam	293
				Lorazepam	53
				Oxazepam	379
BZO	200	570784[j]	False Positive	7-aminoclonazepam	1134
				Nordiazepam	63
				Oxazepam	124
				Temazepam	90
BZO	200	569935[j]	False Positive	Nordiazepam	68
				Oxazepam	244
				Temazepam	93
BZO	200	585873[j]	False Positive	Alprazolam-OH	105
				7-aminoclonazepam	2500
BZO	200	570860[j]	False Positive	Nordiazepam	83
				Oxazepam	218
				Temazepam	126
BZO	200	570941[j]	False Positive	Alprazolam-OH	126
BZO	200	578527[j]	False Positive	Alprazolam-OH	129
				7-aminoclonazepam	146
BZO	200	578563[i]	False Negative	Lorazepam	214

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

Discordant sample resolution

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[k]**	11	99

[k] 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)
COC	150	569915[k]	COC False Positive	Benzoylecgonine	113
COC	150	579796[k]	False Positive	Benzoylecgonine	126
COC	150	579821[k]	False Positive	Benzoylecgonine	128
COC	150	569790[k]	False Positive	Benzoylecgonine	129
COC	150	570955[k]	False Positive	Benzoylecgonine	144
COC	150	577368[k]	False Positive	Benzoylecgonine	144

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

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[l]**	0
	Positive	0	**1[m]**	10	98

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

[m] 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[l]	False Positive	EDDP	76
EDDP	100	572432[m]	False Negative	EDDP	100
EDDP	100	572426[m]	False Negative	EDDP	110

[l] Patient specimen with Specimen ID 572444 was found to be positive despite a near threshold negative result
[m] Patient specimens with Specimen IDs 572432 and 572426 were found to be negative despite a near threshold positive result

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[n]**
	Positive	0	**8[o]**	11	98

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

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[o]	False Positive	Hydrocodone	353
OPI	300	570415[o]	False Positive	Oxycodone	24859
				Oxymorphone	217
OPI	300	586327[o]	False Positive	Morphine	228
OPI	300	582860[o]	False Positive	Hydrocodone	469
OPI	300	572488[o]	False Positive	Morphine	239
OPI	300	586330[o]	False Positive	Morphine	260
OPI	300	582932[o]	False Positive	Hydrocodone	488
				Hydromorphone	67
OPI	300	586329[o]	False Positive	Morphine	285
OPI	300	572644[p]	False Negative	Morphine	2097
				Oxycodone	2674
				Oxymorphone	137

[o] 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
[p] 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.

Discordant sample resolution

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[q]**	0
	Positive	0	**1[r]**	8	99

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

[r] Patient specimen with Specimen ID 570021 was 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)
THC	50	570021[r]	False Positive	11-nor-9-Carboxy-delta 9-THC	31
THC	50	570366[q]	False Negative	11-nor-9-Carboxy-delta 9-THC	51
THC	50	575089[q]	False Negative	11-nor-9-Carboxy-delta 9-THC	56
THC	50	569400[q]	False Negative	11-nor-9-Carboxy-delta 9-THC	63

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

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

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[s]**
	Positive	**1[t]**	**10[u]**	11	95

[s] Patient specimen with Specimen ID 586694 was found to be negative despite a high positive result

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

[u] 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

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[v]	False Positive	Desipramine	0
TCA	1,000	586353[u]	False Positive	Desipramine	637
TCA	1,000	585878[u]	False Positive	Desipramine	639
TCA	1,000	582936[u]	False Positive	Amitriptyline	385
				Nortriptyline	160
TCA	1,000	572581[u]	False Positive	Amitriptyline	149
				Nortriptyline	512
TCA	1,000	585866[u]	False Positive	Desipramine	680
TCA	1,000	586232[u]	False Positive	Desipramine	727
TCA	1,000	585830[u]	False Positive	Desipramine	730
TCA	1,000	585879[u]	False Positive	Desipramine	758
TCA	1,000	582925[u]	False Positive	Amitriptyline	162
				Nortriptyline	599
TCA	1,000	585874[u]	False Positive	Desipramine	608
				Doxepin	238
TCA	1,000	586694[w]	False Negative	Desipramine	1646

[u] 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

[v] 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 13.6% of the assay threshold).

[w] 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

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ASSISTANCE

If you have any questions regarding the use of this product, please contact Quidel Technical Support at 1.800.874.1517 (in the U.S. or Canada) or technicalsupport@quidel.com. If outside the U.S. or Canada, contact your local distributor or one of the Technical Support Centers listed below. You may also contact us at quidel.com.

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94600 – Quidel Triage TOX Drug Screen, 94600

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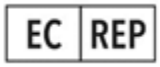
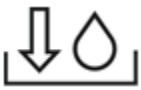
Revision Changes:

- Add the compounds Metharbital, *p*-Hydroxyphenobarbital, and Talbutal to BAR Specificity Table.
- Add the compound Alprazolam glucuronide-OH to BZO Specificity Table.
- Amended the Assistance Section to include the contact information for Canada.
- Removed statements for obtaining electronic instructions for use from website or local Quidel affiliate.

ENSRC26516enC
PN: 26516en Rev. C 2020/05

GLOSSARY

	
Catalogue number	CE mark
	
Authorized representative in the European Community	Batch code
	
Use-by date	Manufacturer
	
Date of manufacture	Temperature limit
	
Intended use	Consult instructions for use
	
In vitro diagnostic medical device	Test device
	
Do not re-use	Contents/contains
	
Prescription Use Only	

 Patient number	 Transfer pipette
 CODE CHIP module	 Printer paper
 Peel open here	 Add sample immediately after opening foil pouch
 Use urine sample only	 Add sample here