E. Effect of Specimen pH

Drug sample solutions with 50% below and 50% above cutoff concentrations were adjusted to pH 4-9 and tested using DrugCheck Dip Drug Test. An unaltered sample was used as a control. The results demonstrate that varying ranges of specimen pH do not interfere with the performance of the test.

F. Effect of Specimen Specific Gravity

Drug sample solutions with 50% below and 50% above cutoff concentrations were adjusted to specific gravity 1.003-1.04 and tested using DrugCheck Dip Drug Test. An unaltered sample was used as a control. The results demonstrate that varying ranges of specimen specific gravity do not interfere with the performance of the test.

BIBLIOGRAPHY OF SUGGESTED READING


ASSAY PROCEDURE FOR DRUG TEST

Preparation
1. If specimen, control, or test devices have been stored at refrigerated temperatures, allow them to warm to room temperature before testing.
2. Do not open test device pouch until ready to perform the test.

Testing
1. Remove the card test device from the sealed pouch write the donor name of 83 in the section provided, and then remove the cap to expose the sampling tips.
2. Immerse the sampling tips into the urine specimen for about 15 seconds, and then place the test device on a flat surface with the cap on.
3. Read results of drugs of abuse tests in 5 minutes. Do not interpret result after 10 minutes. Refer to interpretation of results section.

QUALITY CONTROL

An internal procedural control is included in the test device. A line must form in the Control band region regardless of the presence or absence of drugs or metabolites. The presence of the line in the Control region indicates that sufficient sample volume has been used and that the reagents are migrating properly. If the line in the Control region does not form, the test is considered invalid and must be repeated.

To ensure proper kit performance, it is recommended that the DrugCheck Dip Drug Test device be used by the following external controls with each new lot of product.

PERFORMANCE CHARACTERISTICS

A. Accuracy

The accuracy of the DrugCheck Dip Drug Test was evaluated in comparison to commercially available drug screen tests and GC/MS. Setty 660 negative urine samples collected from presumed non-user volunteers were tested by both DrugCheck Dip Drug Test and commercially available drug screen tests. Of these negative urine samples tested, all were correctly identified as negative by both methods. In a separate study, positive urine samples, obtained from clinical laboratories where the drug concentrations were determined by GC/MS (HPLC for THC), were tested by DrugCheck Dip Drug Test and commercial drug screen tests. The results of accuracy study are presented below:

<table>
<thead>
<tr>
<th>Drug</th>
<th>DrugCheck Dip Drug Test</th>
<th>Commercial Drug Screen Test</th>
<th>GC/MS</th>
</tr>
</thead>
<tbody>
<tr>
<td>AMP</td>
<td>96.8%</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>BOL</td>
<td>96.8%</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>BZO</td>
<td>98.6%</td>
<td>100%</td>
<td>100%</td>
</tr>
</tbody>
</table>
| C/ 

**SPECIMENS COLLECTION AND HANDLING**

Fresh urine does not require any special handling or pre-treatment. A fresh urine sample should be collected in the container provided. Alternatively, a clean, dry plastic or glass container may be used for specimen collection. If the specimen will not be tested after the specimen collection, the specimen may be refrigerated at 2-8°C up to 2 days or frozen at -20°C for longer period of time. Specimens that have been refrigerated must be equilibrated to room temperature prior to testing. Specimens previously frozen must be thawed and mixed thoroughly prior to testing.

Note: Urine specimens and all materials coming in contact with them should be handled and disposed of as if capable of causing a convincing infection. Avoid contact with skin by wearing gloves and proper laboratory attire.

**ASSAY PROCEDURE FOR DRUG TEST**

**Preparation**
1. If specimen, control, or test devices have been stored at refrigerated temperatures, allow them to warm to room temperature before testing.
2. Do not open test device pouch until ready to perform the test.

**Testing**
1. Remove the card test device from the sealed pouch write the donor name of 83 in the section provided, and then remove the cap to expose the sampling tips.
2. Immers the sampling tips into the urine specimen for about 15 seconds, and then place the test device on a flat surface with the cap on.
3. Read results of drugs of abuse tests in 5 minutes. Do not interpret result after 10 minutes. Refer to interpretation of results section.

**QUALITY CONTROL**

An internal procedural control is included in the test device. A line must form in the Control band region regardless of the presence or absence of drugs or metabolites. The presence of the line in the Control region indicates that sufficient sample volume has been used and that the reagents are migrating properly. If the line in the Control region does not form, the test is considered invalid and must be repeated.

To ensure proper kit performance, it is recommended that the DrugCheck Dip Drug Test device be used by the following external controls with each new lot of product and each new shipment. External controls are available from commercial sources. Additional testing may be necessary to comply with the requirements according to organizations and/or local, state, and/or federal regulations.

**LIMITATIONS OF PROCEDURE**

* The assay is designed for use with human urine only.
* A positive result with any of the tests indicates only the presence of a drug/metabolite and does not indicate or measure intoxication.
* There is a possibility that technical or procedural error as well other substances as factors not listed may interfere with the test and cause false results. See SPECIFICITY for lists of substances that will produce positive results, and those that do not interfere with test performance.
* If adulteration is suspected, the test should be repeated with new sample.

**PERFORMANCE CHARACTERISTICS**

**A. Accuracy**

The accuracy of the DrugCheck Dip Drug Test was evaluated in comparison to commercially available drug screen tests and GC/MS. Setty 660 negative urine samples collected from presumed non-user volunteers were tested by both DrugCheck Dip Drug Test and commercially available drug screen tests. Of these negative urine samples tested, all were correctly identified as negative by both methods. In a separate study, positive urine samples, obtained from clinical laboratories where the drug concentrations were determined by GC/MS (HPLC for THC), were tested by DrugCheck Dip Drug Test and commercial drug screen tests. The results of accuracy study are presented below: