**INTENDED USE**

The EarlyDETECT™ Alcohol Rapid Test is intended for the rapid semi-quantitative determination of ethyl alcohol in human saliva. The test is a rapid enzymatic method to detect the presence of alcohol in saliva for blood alcohol concentration (BAC) greater than 0.02%.

**SUMMARY AND EXPLANATION OF TEST**

Alcohol intoxication can lead to loss of alertness, coma, death and as well as birth defects. The BAC at which a person becomes impaired is variable. The United States Department of Transportation (DOT) has established a BAC of 0.02% (0.08% in the US) as the cut-off level at which an individual is considered positive for the presence of alcohol.

**DETERMINATION OF ETHYL ALCOHOL IN SALIVA**

The determination of ethyl alcohol in saliva is commonly used for measuring legal impairment, alcohol poisoning, etc. Gas chromatography techniques and enzymatic methods are commercially available for the determination of ethyl alcohol in human fluids. The EarlyDETECT™ Alcohol Rapid Test is designed as the screen method to rapidly determine if the BAC is higher than 0.02% by testing saliva specimens, as specified by DOT.

**INTERFERENCE STUDY**

The following substances were added to sample which had alcohol levels of 0 and 0.08%. None of the substances at concentration tested interfered in the EarlyDETECT™ Alcohol Rapid Tests. The results have been tabulated below.

**TANNIC ACID**

- *Tannic acid Polyphenolic Compounds Uric acid Oxalic acid Strong oxidizers Ascorbic acid Mercaptans Bilirubin* 

**INTERFERENCE STUDY:**

The results of inter-lot reproducibility studies clearly demonstrated that there was no appreciable inter-lot variation when testing both positive and negative samples across three different lots of EarlyDETECT™ Alcohol Rapid Test.

**PERFORMANCE CHARACTERISTICS**

For the EarlyDETECT™ Alcohol Rapid Tests, within-lot and inter-lot reproducibility studies were performed. The results of the within-lot reproducibility studies clearly showed excellent reproducibility for all positive and negative saliva samples using one lot of EarlyDETECT™ Alcohol Rapid Tests. The results of inter-lot reproducibility studies clearly demonstrated that there was no appreciable inter-lot variation when testing both positive and negative samples across three different lots of EarlyDETECT™ Alcohol Rapid Test.

**BIBLIOGRAPHY**

- Caffeine
- National highway traffic safety administration NHTSA),  DOT , Federal Register. 59:147, August 1994, pp 22382-90
- **EarlyDETECT™** Alcohol Rapid Test is designed for in vitro detection use with human saliva only. A positive result indicates only the presence of alcohol and does not indicate or measure intoxication.

**ASSAY PROCEDURES**

1. Do not open foil pouch until ready to begin testing. Refrigerated test device should be allowed to equilibrate to room temperature (15-25°C) before pouch is opened.
2. Remove the test device from the sealed foil pouch by tearing along the notch.
3. Saturate the reactive pad by dipping the reaction pad into the saliva specimen collected in a spum cup, or by applying saliva directly to the reaction pad. After 10 seconds, shake off the excess saliva.
4. Immediately start timer and at 2 minutes, compare the reactive pad with the provided colored chart.

**INTERPRETATION OF RESULTS**

0% 0.02% 0.08% 0.30%

**LIMITATIONS OF PROCEDURE**

- There is a possibility that technical or procedural errors as well as other substances in certain foods and medicines may interfere with the test and cause false results. Please refer to the "Interference" section for a list of substances that may interfere with the test.
- Aldehydes, such as benzaldehyde or other strong oxidizing agents, may produce erroneuse test results when added to saliva samples, regardless of the analysis method used. If an adulteration is suspected, a fresh saliva sample should be used.

**EXPECTED RESULTS**

The EarlyDETECT™ Alcohol Rapid Test is a semi-quantitative assay. Identity of alcohol in saliva at a concentration of 0.02% BAC.

**PROCESS AND QUALITY CONTROL**

Good Laboratory Practice recommends the daily use of control material to validate the reliability of device. Commercially available controls that contain sodium deoxycholate that will inhibit the enzyme activity cannot be used with this test. The EarlyDETECT™ Alcohol Rapid Test may be qualified by using a test solution prepared by adding 10 drops of ethyl alcohol into 8 oz of distilled water. This solution would show a distinct positive result.

**PERFORMANCE CHARACTERISTICS**

**Sensitivity:** The EarlyDETECT™ Alcohol Rapid Tests have been designed for detection of alcohol in saliva at the detection sensitivity of 10mg/dL (0.08%), as suggested by DOT. In sensitivity studies performed, samples with concentrations of alcohol equal to or higher than 10mg/dl were identified as positive results for all samples. Thus, the cut-off level of the EarlyDETECT™ Alcohol Rapid Test was determined to be 10mg/dl.

**Precision:** In order to determine the precision of EarlyDETECT™ Alcohol Rapid Tests. Within-lot and inter-lot reproducibility studies were performed. Results of the within-lot reproducibility studies clearly showed excellent reproducibility for all positive and negative saliva samples using one lot of EarlyDETECT™ Alcohol Rapid Tests. The results of inter-lot reproducibility studies clearly demonstrated that there was no appreciable inter-lot variation when testing both positive and negative samples across three different lots of EarlyDETECT™ Alcohol Rapid Test.

**STORAGE AND STABILITY**

- These compounds are not normally present in saliva to interfere with the test.
- The precautions step must be taken so that these materials are not introduced into the mouth during the 10 minute period preceding the test.

**WAKINGS AND PRECAUTIONS**

- For in vitro use only.
- Do not use a test device beyond the expiration date imprinted on the outside of the foil pouch.
- Avoid the reactive pad could be observed in less than 20 seconds after the tip was contacted with saliva samples with the ethyl alcohol concentration greater than 0.02%. It should be pointed out that other alcohol analogs containing the ethyl alcohol residues may also produce a positive result.
- Avoid contact with skin by wearing gloves and proper laboratory attire. Properly handle and dispose of all used test devices in an approved biohazard container.
- The product is sensitive to the presence of alcohol and moisture. After opening the package, the test device should be used immediately.

**SAMPLE COLLECTION AND PREPARATION**

- Nothing should be placed into the mouth of the subject for at least 10 minutes prior to saliva collection. This includes food, drink, tobacco products or other materials.
- Saliva samples may be potentially infectious. Avoid contact with skin by wearing gloves and proper laboratory attire.

**ASAY PROCEDURE**

1. Remove the test device from the sealed foil pouch by tearing along the notch.
2. Saturate the reactive pad by dipping the reaction pad into the saliva specimen collected in a spum cup, or by applying saliva directly to the reaction pad. After 10 seconds, shake off the excess saliva.
3. Immediately start timer and at 2 minutes, compare the reactive pad with the provided colored chart.

**INTERPRETATION OF RESULTS**

- Positive: A distinct color developed over the test pad. The positive result indicates that the concentration of ethyl alcohol in saliva is in 0.02% or higher.
- Invalid: The test should be considered invalid if only the edge of the reactive pad turned color that might be absorbed to insufficient sampling. The subject should be re-tested.