

OraSure Technologies, Inc.

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Product Instructions for Q.E.D.® A150 Ethanol Control

3001-1071 rev. 02/15

Intended Use

OraSure Technologies Q.E.D.® A150 Ethanol Controls are intended to be used as a performance control in the determination of alcohol in saliva.

Summary and Principle

The use of quality control materials to monitor assay performance and reliability has been well established.

Contents

Catalog Number 31150S: 2 x 5 mL vials. Each vial contains an aqueous solution of ethanol with preservatives.



Precautions

For *in vitro* diagnostic use.

Reagent Preparation and Storage

OraSure Technologies Q.E.D.® A150 Ethanol Control is ready to use. No additional preparation is required.



Store at room temperature 15-30°C (59-86°F).

Unopened controls are stable until the date printed on the vial label. Replace the cap tightly immediately after use.

Procedure








OraSure Technologies recommends that you use controls on each new lot of Q.E.D.® tests. Substitute the control for saliva sample. Compare the Q.E.D.® test result to the Expected Range below:

EXPECTED RANGE	
Constituent	Expected Range
Ethanol	0.075 - 0.130%
	75 - 130 mg/dL

Interpreting Test Results

The expected range is intended as a guideline to assess assay performance and reliability. Variations in user technique, reagent lot numbers and other systematic and random errors can affect the results you achieve. Contact our Customer Service Department if your control values fall outside the expected range.

EXPLANATION OF SYMBOLS

ABS PACK	Absorbent Packet	SALIVA	Saliva
COL DEVICE	Collection Device	TEST +	Test Positive
CONTENTS	Contents	TEST DEVICE	Test Device
DYNAMIC RANGE	Dynamic Range	LOT	Batch Code
EC REP	Authorized Representative in the European Community		Caution, Consult Accompanying Documents
ETHANOL CONTROL	Ethanol Control		Consult Instructions for Use
IVD	<i>In Vitro</i> Diagnostic Medical Device		Do Not Reuse
PACK INSERT	Package Insert		Manufacturer
PN	Part Number		Poison
POUCH	Pouch		Temperature Limitation
REF	Catalog Number		Use By

**For additional assistance, call OTI Technical Service in the
USA: (800) 869-3538 • Outside the USA 1+610-882-1820**