Intercept® *i2he*™ CANNABINOIDS ORAL FLUID ASSAY APPLICATION

Thermo Scientific Indiko, Indiko Plus

Catalog No. 1001-0390

The Intercept *i2he* Cannabinoids Oral Fluid Assay is intended for use in the qualitative determination of Cannabinoids in human oral fluid at a cutoff concentration of 3 ng/mL in neat oral fluid. The specimen must be collected exclusively with the Intercept *i2he* Oral Fluid Collection Device. The assay is calibrated against *l*-Δ^9 tetrahydrocannabinol (*l-isomer* Δ^9 THC) and performed on clinical chemistry analyzers. This device is not intended for use for clinical diagnostic applications.

For Forensic Use Only.

Intended Use

The information provided in this application sheet is intended as a supplement to the package insert. Refer to the package insert for information on intended use, reagent storage, reagent preparation, specimen collection, specimen storage, quality control, and additional performance data.

Ordering Information

Item	Size	Catalog Number
Intercept *i2he* Cannabinoids (THC) Oral Fluid Assay	65 mL	1001-0390
Intercept *i2he* THC Oral Fluid Negative Calibrator	10 mL	1001-0399
Intercept *i2he* THC Oral Fluid Cutoff Calibrator	5 mL	1001-0398
Intercept *i2he* THC Oral Fluid Control Set	10 mL x 2	1001-0397

To place an order or for technical service contact:

OraSure Technologies, Inc.
220 East First Street
Bethlehem, PA 18015
U.S. Toll free: (800) 673-7873
Outside the U.S.: (001) 610-882-1820

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Reagent Preparation and Storage

Refer to package insert for information on reagent preparation and storage.

Procedure for Analyzer

Refer to operator's manuals for information on analyzer operation.

Dispense adequate amounts of R1 and R2 into appropriate containers.
Make sure that the reagents have equilibrated to the temperature of the analyzer reagent compartment before starting analysis.

Results and Data Interpretation

Refer to the package insert for information on results and data interpretation.

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Intercept *i2he* Cannabinoids (THC) Oral Fluid Assay – Qualitative
Thermo Scientific Indiko, Indiko Plus System Parameters

Info	
Tag	10019895IFU
Full name	OraSure Cannabinoids OFT Assay
In use	Yes
Type	Photometric
Online name	User-defined
Acceptance	User-defined
Result unit	ng/mL
Number of decimals	1
Correction factor	1
Correction bias	0
Sample type	Oral Fluid

Flow						
	Blank type	No	Primary dilution 1+	0	Dispensed volume	128
Reagent	Reagent	Volume (µL)	Dispense with	Extra volume (µL)	Syringe speed	Replacing reagent
	OS THC R1	55	Extra	20	Slow	None
	Barcode ID	Alarm limit (mL)	Onboard stability (days)			
		2.0	30			
Sample	Volume (µL)	Dispense with	Extra volume (µL)	Extra wash		
	18	Water	15	No		
Incubate	Time (sec)	Actual time(sec)				
	300	297				
Reagent	Reagent	Volume (µL)	Dispense with	Extra volume (µL)	Syringe speed	Replacing reagent
	OS THC R2	55	Extra	20	Slow	None
	Barcode ID	Alarm limit (mL)	Onboard stability (days)			
		2.0	30			
Incubate	Time (sec)	Actual time(sec)				
	240	234				
Kinetic measurement	Main wavelength (nm)	Side wavelength (nm)	Residual net abs. (A)	Curve direction	Measurement type	Nonlinearity (ng/mL)
	575	660	0	Ascending	Linear	1
	Measurement time (sec)	Points/interval	Actual meas. time (sec)	Rate check in use	Max rate (A/min)	Nonlinearity (%)
	72	9/9	72	No	*	99

Dilution			**Limits**				
				Measuring Range (ng/mL)		Next dilution ratio (1+)	
	Dilution with	Water		Min	Max	Low	High
	Primary dilution 1+	0	Primary Dilution	*	*	*	*
			Test limit	*	*	ng/mL	
			Critical limit	*	*	ng/mL	
			Init. abs.	-0.5	3	A	
			Cut Off Levels				
			Limit 1		Limit 2		
			1		*		ng/mL

Calibration						
Calibration type	Linear				Abs error (A)	0.02
Repeat time (days)	0				Rel. error (%)	20
Points/calibrator	Duplicate				Factor limit min.	*
Acceptance	User-defined				Factor limit max.	*
					Bias limit min.	*
Nbr	Calibrator	Current lot	Concentration	Dilution 1+	Bias limit max.	*
1	OS THC Neg	User-defined	0	0		
2	OS THC C/O	User-defined	1	0	Concentration axis	Linear
					Response axis	Linear

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