

Kit Configuration

P/N W150135	1 x 100 mL Antibody/Substrate Reagent A (R1)
	1 x 100 mL Enzyme Conjugate Reagent E (R2)

Reagent Preparation

P/N W150039: Reagents are ready to use. Pour R1 and R2 in the appropriate bottles and place them in the reagent tray.

In use Stability

On Board: 30 days

Specimen

Urine

Calibration

Use: Negative Calibrator Cat. No.W151664

Low Calibrator Cat. No.W15034

MultiDrug Calibrator 1 Cat. No.W151588

MultiDrug Calibrator 2 Cat. No.W151591

MultiDrug Calibrator 3 Cat. No.W151594

Recalibrate every 21 days or when a new lot of reagent is used.

Quality Control

MGC Clinical DAU Control Set Cat. N°.15100201 (2 levels)

Calculation and Analytical Results

The results concentration is automatically calculated by the instrument against the Calibration curve. For detailed description, refer to the Instrument settings and to the I Lab 350 Operator Manual.

Semiquantitative results

A rough estimate of drug concentration in the samples can be obtained by running a standard curve with all calibrators and quantifying samples off the standard curve.

References / Literatur / Bibliografía / Bibliographie / Bibliografia /

See package insert inclosed in the kit

Performance Characteristics

The performance below were obtained working with a cutoff of 300 ng/mL

Limitation/Interfering Substances

A positive result by this assay should be confirmed by another non immunological method such as GC, TLC or GC/MS.

It is possible that other substances and/or factors (eg, technical or procedural) not listed in the specificity table (see package insert) may interfere with the test and cause false results.

Precision

	Samples/Runs	Mean (ng/mL)	CV(%)	Mean (ng/mL)	CV(%)	Mean (ng/mL)	CV%
Within Run	5/10	221	2.2	307	2.6	441	1.8
Total	5/10	221	4.1	307	5.3	441	5.1

Minimun Detection Limit

2 ng/mL

Instrument Settings

Chemistry Parameters				R1			
Method	<input type="text"/>			Reagent Name	<input type="text" value="OPIATE"/>	Volume	<input type="text" value="100 μL"/>
Name	<input type="text" value="OPI300"/>			R2	<input type="text" value="enable"/>		
Unit	<input type="text" value="ng/mL"/>			Reagent Name	<input type="text" value="OPIATE"/>	Volume	<input type="text" value="100 μL"/>
Assay Type	<input type="text" value="Rate"/>			Wash	<input type="text" value="disable"/>	Reagent Name	<input type="text"/>
				Diluent	<input type="text" value="disable"/>	Reagent Type	<input type="text"/>
				Reagent Name	<input type="text"/>		
Measuring Points	1 <input type="text" value="disable"/>	start	<input type="text"/>	Decimal Points	<input type="text" value="0"/>		
		end	<input type="text"/>	Normal Range	<input type="text" value="299.0 - 300"/>		
	2 <input type="text" value="enable"/>	start	<input type="text" value="15"/>				
		end	<input type="text" value="20"/>				
Wave Length							
Prim	<input type="text" value="340"/>	Sec	<input type="text" value="405"/>	Technical Range (Conc)	<input type="text" value="0 - 4000"/>		
				mAbs/10	<input type="text" value="-30000 / 30000"/>		
Sampling Volume	<input type="text" value="12 μL"/>						
Dilution	<input type="text" value="disable"/>		RPT Wash		(R1) <input type="text" value="Sys Water"/>		
	<input type="text"/>	<input type="text"/>			(R2) <input type="text" value="Sys Water"/>		
Rerun (High)	<input type="text" value="μL"/>						
Dilution	<input type="text" value="disable"/>		Instrument Factor a		<input type="text" value="1"/>	b	<input type="text" value="0"/>
	<input type="text"/>	<input type="text"/>	Stirring Speed		R1 <input type="text" value="mid"/>	R2	<input type="text" value="mid"/>
Rerun (Low)	<input type="text" value="μL"/>						

Calibration Checks

** Duplicate Limit	<input type="text"/>	** mAbs/10	Sampling Method for Standards				
** Sensitivity Limit	<input type="text"/>	** mAbs/10	<input type="text"/>	Duplicate			
			<input checked="" type="checkbox"/>	Triplicate			
** Linearity Limit	<input type="text"/>	** %	Blank measurement				
** Prozone Limit	<input type="text"/>	upper	<input checked="" type="checkbox"/>	Disable Reagent blank			
SL1-S	**	SL1-F **	<input type="text" value="None"/>				
SL2-S	**	SL2-F **	Reagent blank measurement at calibration				
Sens	<input type="text"/>		<input type="text"/>				
		mAbs/10	<input type="text"/>				
<input checked="" type="checkbox"/> Absorbance Limit			** Multiplex measurement is the same as standards				
Reaction Limit	<input type="text" value="Increase"/>	Reagent Blank Limit Checks					
Limit	<input type="text" value="25000"/>	mAbs/10	<input type="text"/>		** Duplicate limit		
			<input type="text" value="50"/>		mAbs/10		

Calibration

Method	<input type="text"/>	Name	<input type="text" value="OPIATE"/>	Interval	<input type="text" value="21"/>	days
Calculation	<input type="text" value="Point to Point"/>					
	Conc	WORK	MASTER	Lot No		
S1	<input type="text" value="0"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	K	<input type="text" value="N/A"/>
S2	<input type="text" value="300"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>		
S3	<input type="text" value="1000"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>		
S4	<input type="text" value="2000"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>		
S5	<input type="text" value="4000"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>		
S6	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>		

Reagent Registration

Reagent Code	<input type="text" value="0145"/>					
Reagent Name	<input type="text" value="OPIATE"/>					
	Volume (L)		Volume (S)		Stability Check	
R1	<input checked="" type="checkbox"/>	enable	<input type="text"/>	mL	<input checked="" type="checkbox"/>	enable
R2	<input checked="" type="checkbox"/>	enable	<input type="text"/>	mL	<input checked="" type="checkbox"/>	enable
			<input type="text"/>	mL		Term
						<input type="text" value="30"/>
						days

** Operator definable N/A not applicable to this test