

MVP Summary**SIEMENS****ADVIA 2400 (S/N CA1275000100010) / serum Barbiturate (sBRB)**

Prepared for: **Theranos, Inc**
 Contact: Adam Rosendorff, M.D. 650-865-4412

Prepared by: Debra Iott, MT(ASCP)
 Verification Date: November 21, 2014

New Method

ADVIA 2400 (S/N CA1275000100010)
serum Barbiturate (ug/mL)

Traceability:

Reference Range: 0.000 - 1.000
 Analytical Range: 0.000 - 1,000.000
 Reagent 1: 184
 Reagent 2: 183

Reference Range Verification

Number of Samples: 30	Range of Observations: 0.000 to 0.010
Mean: 0.000	2.5 to 97.5 Percentiles: 0.00 to 0.00
Median: 0.000	2 SD Range: -0.003 to 0.004
SD: 0.002	Outlier Limits: 0.00 to 0.00
CV%: 547.7	95th Percentile: 0.00

Precision/Accuracy

Control	Level	N	Assayed Mean	%CV	Accuracy
60558914	1	10	0.677	1.00	Within Acceptable Limits
60656591	2	10	1.458	0.78	Within Acceptable Limits

I have reviewed the MVP data for serum Barbiturate on the ADVIA 2400 (S/N CA1275000100010) and approve the use of this test in our facility.

DocuSigned by:

 Laboratory Manager/Director: _____

Date: 1/11/2015

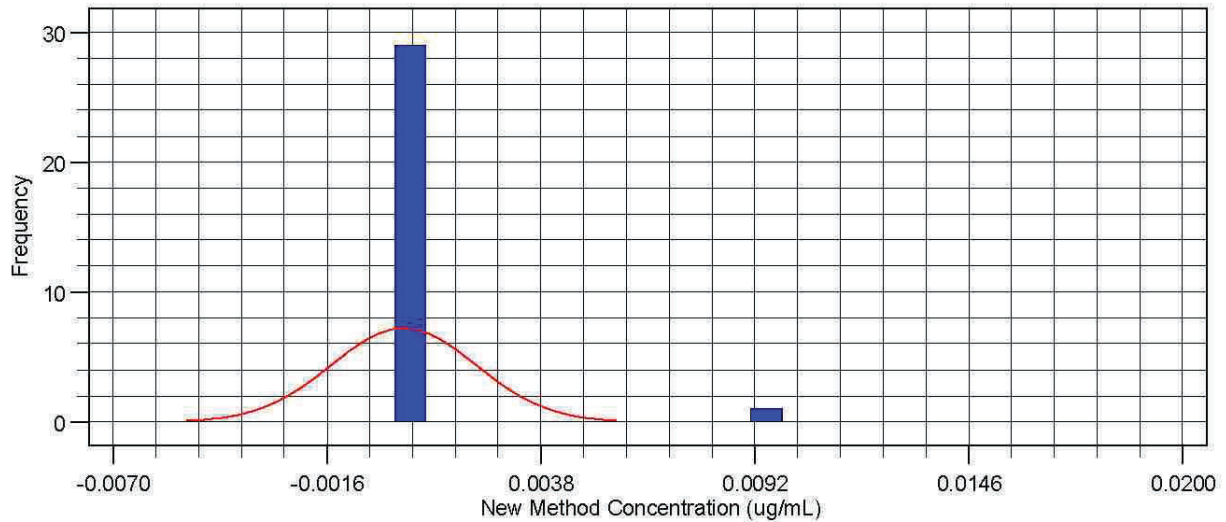
MVP Reference Range Verification**SIEMENS****ADVIA 2400 (S/N CA1275000100010) / serum Barbiturate (sBRB)**

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 Reagent 1: 184
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**Verification of Reference Interval**

Proposed Range (ug/mL)	0.000 - 1.000
Results (Total / Excluded)	30 / 0
Max Limit / Observations Outside	10.0% / 0.0%
Passed	Yes

Number of Samples	30
Mean	0.000
Median	0.000
SD	0.002
CV%	547.7

Range of Observations	0.000 to 0.010
2.5 to 97.5 Percentiles	0.00 to 0.00
2 SD Range	-0.003 to 0.004
Outlier Limits	0.00 to 0.00
95th Percentile	0.00

Observations sorted by Sample ID. (X = Excluded from calculations, L = Low Outlier, H = High Outlier)

Sample ID	Result	Sample ID	Result	Sample ID	Result	Sample ID	Result
MALE16	0.000	MALE24	0.000	FEMALE02	0.000	FEMALE09	0.000
MALE17	0.000	MALE25	0.000	FEMALE03	0.000	FEMALE10	0.000
MALE18	0.000	MALE26	0.000	FEMALE04	0.000	FEMALE11	0.000
MALE19	0.000	MALE27	0.000	FEMALE05	0.000	FEMALE12	0.000
MALE20	0.000	MALE28	0.000	FEMALE06	0.000	FEMALE13	0.000
MALE21	0.000	MALE29	0.000	FEMALE07	0.000	FEMALE14	0.000
MALE22	0.000	MALE30	0.000	FEMALE08	0.000	FEMALE15	0.000
MALE23	0.000	H FEMALE01	0.010				

MVP Precision/Accuracy**SIEMENS****ADVIA 2400 (S/N CA1275000100010) / serum Barbiturate (sBRB)**

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Analytical Range: 0.000 - 1,000.000

Reagent 1: 184

Reagent 2: 183

Within Run Precision

<u>Control</u>	<u>Level</u>	<u>N</u>	<u>Assayed Mean</u>	<u>SD</u>	<u>%CV</u>
60558914	1	10	0.677	0.007	1.00
60656591	2	10	1.458	0.011	0.78

Accuracy

<u>Control</u>	<u>Level</u>	<u>N</u>	<u>Assayed Mean</u>	<u>Published Control Range</u>	<u>Comment</u>
60558914	1	10	0.677	0.000 - 0.990	Within Acceptable Limits
60656591	2	10	1.458	1.000 - 10.000	Within Acceptable Limits

MVP Detailed Data - Control Samples**SIEMENS****ADVIA 2400 (S/N CA1275000100010) / serum Barbiturate (sBRB)**

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serum Barbiturate (ug/mL)

Traceability:

Reference Range: 0.000 - 1.000

Analytical Range: 0.000 - 1,000.000

Reagent 1: 184

Reagent 2: 183

Run N°	Control Lot Number	Level	Rep	Concentration	Include	Comments
1	60558914	1	1	0.670	Yes	ug/mL
1	60558914	1	2	0.670	Yes	ug/mL
1	60558914	1	3	0.680	Yes	ug/mL
1	60558914	1	4	0.670	Yes	ug/mL
1	60558914	1	5	0.680	Yes	ug/mL
1	60558914	1	6	0.670	Yes	ug/mL
1	60558914	1	7	0.680	Yes	ug/mL
1	60558914	1	8	0.680	Yes	ug/mL
1	60558914	1	9	0.690	Yes	ug/mL
1	60558914	1	10	0.680	Yes	ug/mL
	60558914	1		0.677	Yes	Mean
1	60656591	2	1	1.460	Yes	ug/mL
1	60656591	2	2	1.460	Yes	ug/mL
1	60656591	2	3	1.450	Yes	ug/mL
1	60656591	2	4	1.460	Yes	ug/mL
1	60656591	2	5	1.480	Yes	ug/mL
1	60656591	2	6	1.450	Yes	ug/mL
1	60656591	2	7	1.450	Yes	ug/mL
1	60656591	2	8	1.470	Yes	ug/mL
1	60656591	2	9	1.460	Yes	ug/mL
1	60656591	2	10	1.440	Yes	ug/mL
	60656591	2		1.458	Yes	Mean

MVP Detailed Data - Patient Samples (Quantitative Data)**SIEMENS****ADVIA 2400 (S/N CA1275000100010) / serum Barbiturate (sBRB)**Prepared for: **Theranos, Inc**
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Traceability:

Reference Range: 0.000 - 1.000

Analytical Range: 0.000 - 1,000.000

Reagent 1: 184

Reagent 2: 183

Run N°	Sample ID	New Method Concentration	Comparison Concentration	Include	Comments
1	MALE16	0.000		Yes	ug/mL
1	MALE17	0.000		Yes	ug/mL
1	MALE18	0.000		Yes	ug/mL
1	MALE19	0.000		Yes	ug/mL
1	MALE20	0.000		Yes	ug/mL
1	MALE21	0.000		Yes	ug/mL
1	MALE22	0.000		Yes	ug/mL
1	MALE23	0.000		Yes	ug/mL
1	MALE24	0.000		Yes	ug/mL
1	MALE25	0.000		Yes	ug/mL
1	MALE26	0.000		Yes	ug/mL
1	MALE27	0.000		Yes	ug/mL
1	MALE28	0.000		Yes	ug/mL
1	MALE29	0.000		Yes	ug/mL
1	MALE30	0.000		Yes	ug/mL
1	FEMALE01	0.010		Yes	ug/mL
1	FEMALE02	0.000		Yes	ug/mL
1	FEMALE03	0.000		Yes	ug/mL
1	FEMALE04	0.000		Yes	ug/mL
1	FEMALE05	0.000		Yes	ug/mL
1	FEMALE06	0.000		Yes	ug/mL
1	FEMALE07	0.000		Yes	ug/mL
1	FEMALE08	0.000		Yes	ug/mL
1	FEMALE09	0.000		Yes	ug/mL
1	FEMALE10	0.000		Yes	ug/mL
1	FEMALE11	0.000		Yes	ug/mL
1	FEMALE12	0.000		Yes	ug/mL
1	FEMALE13	0.000		Yes	ug/mL
1	FEMALE14	0.000		Yes	ug/mL
1	FEMALE15	0.000		Yes	ug/mL