

۱۴۰۲/۰۳/۲۴

جهت اجرایی نمودن تصدیق عدم دقت روش اندازه گیری TSH با نام شرکت سازنده SIEMENS و شماره سری ساخت ۷۴۵ طبق روش اجرایی QMP- KVS-02-00 براساس CLSI EP-15 نتایج بررسی به قرار زیر است:

**Precision (μIU/mL)**

	Within-Run <sup>1</sup>			Total <sup>2</sup>	
	Mean <sup>3</sup>	SD <sup>4</sup>	CV <sup>5</sup>	SD	CV
1	0.016	0.002	12.5%	0.002	12.5%
2	0.32	0.017	5.3%	0.017	5.3%
3	1.3	0.05	3.8%	0.06	4.6%
4	3.3	0.13	3.9%	0.16	4.8%
5	7.3	0.37	5.1%	0.37	5.1%
6	19	0.73	3.8%	0.85	4.5%
7	39	2.0	5.1%	2.5	6.4%

**1. Input Data**

Run No.	A	B	C	D	E
1	3.46	3.18	3.24	3.71	4.06
2	3.02	2.84	3.62	3.56	4.03
3	3.48	3.41	3.49	3.92	3.46
4	3.32	3.43	3.44	4.04	3.84
5	3.31	3.37	3.52	3.75	3.98
Generic Analysis					
Mean	3.32	3.25	3.46	3.80	3.87
SD	0.18	0.25	0.14	0.19	0.25
CV	5.54	7.63	4.06	4.93	6.36
Outliers Range					
LL	2.75	2.48	3.03	3.22	3.11
UP	3.89	4.01	3.90	4.38	4.64

**2. Analysis Results**

Count	25
Min.	2.84
Max.	4.06
Sum	88.48
Mean	3.54
Median	3.48
Mode	3.46
SD	0.32
CV%	9
W-Count	25
W-Mean	3.54
W-SD	0.32
W-CV%	9

Mean of Means	3.54
Mean of Variances	0.04
Variance of Means	0.08
Total SD	0.34
Total CV	9.52
TEa% value	20
CV% value	Not OK
F-Test	Recommended

Whitin Lab CV%= 9.52%

$$\text{Whitin Run CV\%} = \frac{\sqrt{0.04}}{3.54} * 100 = 5.65$$

براساس CLSI EP 15

(۱) مقادیر CV به دست آمده نسبت به UVL مقادیر CV ارایه شده توسط شرکت سازنده، قابل قبول نیست:

$$\text{Whitin Run CV\%} = 3.9 \times 1.3 = 5.07 < 5.65$$

$$\text{Whitin Lab CV\%} = 4.8 \times 1.3 = 6.24 < 9.52$$

$$\text{Whitin Run UVL} = (1/4 \times 23.7) \times 1.3 = 7.7 > 5.65 \text{ OK}$$

$$\text{Whitin Lab UVL} = (1/3 \times 23.7) \times 1.3 = 10.27 > 9.52 \text{ OK}$$

(۲) اما براساس CV مشتق از خطای کل مجاز ۲۳/۷٪ (DBV) داریم:

برطبق خطای مجاز انتخابی، کیت SIEMENS برای TSH تصدیق می شود.

مدیر کیفیت:

مسئول فنی:

کارشناس فنی:

مسئول کنترل کیفیت:

(Heparin) = 0.95 (Serum) + 0.06  $\mu$ IU/mL  
 $r = 0.999$

(EDTA) = 0.64 (Serum) + 0.02  $\mu$ IU/mL  
 $r = 0.998$

(SST) = 0.99 (Plain Tubes) - 0.11  $\mu$ IU/mL  
 $r = 0.991$

Means:

1.65  $\mu$ IU/mL (Serum)  
 1.62  $\mu$ IU/mL (Heparin)  
 1.07  $\mu$ IU/mL (EDTA)  
 1.52  $\mu$ IU/mL (SST)

**Method Comparison:** The assay was compared to IMMULITE Third Generation TSH on 106 samples. (Concentration range: approximately 0.006 to 60  $\mu$ IU/mL. See graph.) By linear regression:

(IML 2000) = 0.94 (IML) + 0.23  $\mu$ IU/mL  
 $r = 0.985$

Means:

6.4  $\mu$ IU/mL (IMMULITE 2000)  
 6.5  $\mu$ IU/mL (IMMULITE)

## References

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- 2) Lindstedt G, et al. Clinical use of laboratory thyroid tests and investigations. *JIFCC* 1994;6:136-41.
- 3) Mandel SJ, Brent GA, Larsen PR. Levothyroxine therapy in patients with thyroid disease. *Ann Intern Med* 1993;119:492-502.
- 4) Singer PA, Cooper DS, et al. Treatment guidelines for patients with hyperthyroidism and hypothyroidism. *JAMA* 1995;273:808-12.
- 5) Spencer CA, Takeuchi M, Kazarosyan M, et al. Interlaboratory/intermethod differences in functional sensitivity of immunometric assays of thyrotropin (TSH) and impact on reliability of measurement of subnormal concentrations of TSH. *Clin Chem* 1995;41:367-74.
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- 7) Baloch Z, Carayon P, Conte-Devolx B, Demers LM, Feldt-Rasmussen U, Henry JF, et al. Guidelines Committee, National Academy of Clinical Biochemistry (NACB). Laboratory medicine practice guidelines (LMPG). Laboratory support for the diagnosis and monitoring of thyroid disease. *Thyroid* 2003 Jan;13(1):3-126. Also available at [http://www.nacb.org/lmpg/thyroid\\_LMPG\\_Word.stm](http://www.nacb.org/lmpg/thyroid_LMPG_Word.stm) (accessed January 2005).
- 8) Centers for Disease Control. Update: Universal precautions for prevention of transmission of human immunodeficiency virus, hepatitis B virus and other bloodborne pathogens in healthcare settings. *MMWR*, 1988;37:377-82, 387-8.
- 9) Clinical and Laboratory Standards Institute

(formerly NCCLS). Protection of Laboratory Workers From Occupationally Acquired Infections; Approved Guideline - Third Edition. Wayne, PA: Clinical and Laboratory Standards Institute; 2005. NCCLS Document M29-A3.

10) Federal Occupational Safety and Health Administration, Bloodborne Pathogens Standard, 29 CFR 1910.1030.

11) Clinical and Laboratory Standards Institute. *Defining, Establishing, and Verifying Reference Intervals in the Clinical Laboratory; Approved Guideline—Third Edition*. Wayne, PA: Clinical and Laboratory Standards Institute; 2010. CLSI Guideline EP28-A3C.

12) Horn PS, Pesce AJ. Reference Intervals. A User's Guide, Washington, DC: AACC Press; 2005.

13) Reed AH, Henry RJ, Mason WB. Influence of statistical method used on the resulting estimate of normal range. 1971; 17:275-284.

## Technical Assistance

Contact your National Distributor.

[www.siemens.com/diagnostics](http://www.siemens.com/diagnostics)

The Quality System of Siemens Healthcare Diagnostics Products Ltd. is certified to ISO 13485.

## Tables and Graphs

### Precision ( $\mu$ IU/mL)

	Mean <sup>3</sup>	Within-Run <sup>1</sup>		Total <sup>2</sup>	
		SD <sup>4</sup>	CV <sup>5</sup>	SD	CV
1	0.016	0.002	12.5%	0.002	12.5%
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### Linearity ( $\mu$ IU/mL)

	Dilution <sup>1</sup>	Observed <sup>2</sup>	Expected <sup>3</sup>	%O/E <sup>4</sup>
1	16 in 16 <sup>5</sup>	6.4	—	—
	8 in 16	3.1	3.2	97%
	4 in 16	1.6	1.6	100%
	2 in 16	0.86	0.80	108%
	1 in 16	0.42	0.40	105%
2	16 in 16	21	—	—



<u>TEST</u>	<u>POS</u>	<u>ACCESSION #</u>	<u>NAME</u>	<u>RESULT</u>	<u>UNITS</u>	<u>DIL.</u>	<u>CPS</u>	<u>KIT LOT</u>	<u>DATE</u>	<u>TIME</u>
TSH	a-1	0	bio1	0.318	mIU/L	1	272399	745	06/08/2023	10:05:29AM
TSH	a-3	00	bio2	4.13	mIU/L	1	3145064	745	06/08/2023	10:08:14AM
TSH	F-4	p-tsh		3.18	mIU/L	1	2444377	745	06/08/2023	11:40:36AM
TSH	F-4	p-tsh		2.84	mIU/L	1	2189326	745	06/08/2023	11:40:54AM
TSH	F-4	p-tsh		3.41	mIU/L	1	2613072	745	06/08/2023	11:41:13AM
TSH	F-4	p-tsh		3.43	mIU/L	1	2627010	745	06/08/2023	11:41:32AM
TSH	F-4	p-tsh		3.37	mIU/L	1	2586256	745	06/08/2023	11:41:50AM
TSH	A-5	14020301396		1.94	mIU/L	1	1517424	745	06/08/2023	12:21:51PM
TSH	A-9	14020301596		2.67	mIU/L	1	2061991	745	06/08/2023	12:25:14PM
TSH	A-10	14020301597		1.55	mIU/L	1	1219348	745	06/08/2023	12:27:58PM
TSH	A-11	14020301600		0.408	mIU/L	1	342709	745	06/08/2023	12:29:31PM
TSH	B-1	14020301633		1.30	mIU/L	1	1029897	745	06/08/2023	12:38:02PM
TSH	B-6	14020301644		0.965	mIU/L	1	773104	745	06/08/2023	12:40:50PM
TSH	B-9	14020301675		1.26	mIU/L	1	1001112	745	06/08/2023	12:41:30PM
TSH	B-10	14020301676		3.87	mIU/L	1	2956977	745	06/08/2023	12:41:49PM
TSH	B-11	14020301677		2.03	mIU/L	1	1584387	745	06/08/2023	12:42:25PM
TSH	B-12	14020301679		2.66	mIU/L	1	2058355	745	06/08/2023	12:43:38PM
TSH	B-13	14020301680		2.12	mIU/L	1	1648774	745	06/08/2023	12:45:49PM
TSH	B-14	14020301681		2.15	mIU/L	1	1677711	745	06/08/2023	12:47:22PM
TSH	B-15	14020301683		8.23	mIU/L	1	6066742	745	06/08/2023	12:48:16PM
TSH	D-1	14020301685		1.65	mIU/L	1	1292371	745	06/08/2023	12:48:35PM
TSH	D-2	14020301687		4.41	mIU/L	1	3347241	745	06/08/2023	12:49:12PM
TSH	D-3	14020301689		8.78	mIU/L	1	6446931	745	06/08/2023	12:49:13PM
TSH	D-4	14020301690		1.53	mIU/L	1	1204652	745	06/08/2023	12:51:03PM
TSH	D-5	14020301691		1.90	mIU/L	1	1486821	745	06/08/2023	12:51:39PM
TSH	D-6	14020301692		1.85	mIU/L	1	1450537	745	06/08/2023	12:53:47PM
TSH	D-7	14020301693		3.31	mIU/L	1	2544064	745	06/08/2023	12:54:42PM
TSH	D-8	14020301695		0.896	mIU/L	1	720161	745	06/08/2023	12:56:13PM
TSH	D-10	14020301697		2.15	mIU/L	1	1674984	745	06/08/2023	12:57:26PM
TSH	D-11	14020301698		1.19	mIU/L	1	944602	745	06/08/2023	12:58:21PM

<u>TEST</u>	<u>POS</u>	<u>ACCESSION #</u>	<u>NAME</u>	<u>RESULT</u>	<u>UNITS</u>	<u>DIL.</u>	<u>CPS</u>	<u>KIT LOT</u>	<u>DATE</u>	<u>TIME</u>
TSH	a-1	0	bio1	0.342	mIU/L	1	291155	745	06/10/2023	11:18:04AM
TSH	a-3	00	bio2	3.48	mIU/L	1	2668824	745	06/10/2023	11:20:12AM
TSH	E-1	p-tsh		3.24	mIU/L	1	2488312	745	06/10/2023	03:10:13PM
TSH	E-1	p-tsh		3.62	mIU/L	1	2769647	745	06/10/2023	03:11:08PM
TSH	E-1	p-tsh		3.49	mIU/L	1	2677308	745	06/10/2023	03:11:26PM
TSH	E-1	p-tsh		3.44	mIU/L	1	2633373	745	06/10/2023	03:13:35PM
TSH	E-1	p-tsh		3.52	mIU/L	1	2696246	745	06/10/2023	03:14:11PM
TSH	A-11	14020301755		1.46	mIU/L	1	1148143	745	06/10/2023	03:26:58PM
TSH	A-12	14020301756		1.49	mIU/L	1	1177231	745	06/10/2023	03:28:11PM
TSH	A-13	14020301760		1.38	mIU/L	1	1094360	745	06/10/2023	03:30:56PM
TSH	A-14	14020301761		1.42	mIU/L	1	1120418	745	06/10/2023	03:31:14PM
TSH	A-15	14020301762		1.90	mIU/L	1	1485609	745	06/10/2023	03:32:10PM
TSH	B-1	14020301764		3.24	mIU/L	1	2487857	745	06/10/2023	03:32:29PM
TSH	B-2	14020301765		3.41	mIU/L	1	2614587	745	06/10/2023	03:33:24PM
TSH	B-3	14020301767		0.338	mIU/L	1	288265	745	06/10/2023	03:34:01PM
TSH	B-4	14020301772		1.48	mIU/L	1	1162990	745	06/10/2023	03:35:14PM
TSH	B-8	14020301801		0.991	mIU/L	1	792800	745	06/10/2023	03:40:19PM
TSH	B-10	14020301809		0.479	mIU/L	1	397464	745	06/10/2023	03:43:51PM
TSH	B-11	14020301810		2.90	mIU/L	1	2237049	745	06/10/2023	03:47:12PM
TSH	B-12	14020301811		6.60	mIU/L	1	4923296	745	06/10/2023	03:48:07PM
TSH	B-13	14020301812		0.417	mIU/L	1	349538	745	06/10/2023	03:48:45PM
TSH	B-14	14020301813		2.27	mIU/L	1	1767550	745	06/10/2023	03:49:22PM
TSH	B-15	14020301815		1.43	mIU/L	1	1125266	745	06/10/2023	03:50:16PM
TSH	D-1	14020301816		2.62	mIU/L	1	2030176	745	06/10/2023	03:52:06PM
TSH	D-2	14020301817		2.95	mIU/L	1	2272197	745	06/10/2023	03:53:05PM
TSH	D-3	14020301818		0.983	mIU/L	1	786891	745	06/10/2023	03:53:59PM
TSH	D-4	14020301819		2.96	mIU/L	1	2283862	745	06/10/2023	03:55:28PM
TSH	D-5	14020301820		1.69	mIU/L	1	1324034	745	06/10/2023	03:57:29PM
TSH	D-6	14020301823		1.39	mIU/L	1	1096330	745	06/10/2023	03:58:56PM
TSH	D-7	14020301824		1.67	mIU/L	1	1309945	745	06/10/2023	03:59:11PM



<u>TEST</u>	<u>POS</u>	<u>ACCESSION #</u>	<u>NAME</u>	<u>RESULT</u>	<u>UNITS</u>	<u>DIL.</u>	<u>CPS</u>	<u>KIT LOT</u>	<u>DATE</u>	<u>TIME</u>
TSH	F-6	14020302591		3.82	mIU/L	1	2916905	745	06/13/2023	02:41:20PM
TSH	F-7	14020302595		1.94	mIU/L	1	1517272	745	06/13/2023	02:41:38PM
TSH	F-8	14020302596		1.62	mIU/L	1	1274494	745	06/13/2023	02:42:33PM
TSH	F-9	14020302597		1.04	mIU/L	1	829311	745	06/13/2023	02:44:58PM
TSH	F-10	14020302418		2.22	mIU/L	1	1730584	745	06/13/2023	02:46:11PM
TSH	E-1	p-tsh		4.06	mIU/L	1	3095751	745	06/13/2023	02:46:29PM
TSH	E-1	p-tsh		4.03	mIU/L	1	3072874	745	06/13/2023	02:46:48PM
TSH	E-1	p-tsh		3.46	mIU/L	1	2653220	745	06/13/2023	02:48:01PM
TSH	E-1	p-tsh		3.84	mIU/L	1	2935237	745	06/13/2023	02:48:38PM
TSH	E-1	p-tsh		3.98	mIU/L	1	3034696	745	06/13/2023	02:48:56PM
TSH	A-13	14020302583		1.23	mIU/L	1	976418	745	06/13/2023	02:50:45PM
TSH	A-10	14020302573		1.48	mIU/L	1	1165414	745	06/13/2023	02:53:10PM
TSH	A-11	14020302580		1.20	mIU/L	1	955965	745	06/13/2023	02:54:23PM
TSH	A-12	14020302581		6.76	mIU/L	1	5033512	745	06/13/2023	02:55:18PM
TSH	a-3	14020302572		4.23	mIU/L	1	3214754	745	06/13/2023	03:01:02PM