

# COMPARATIVE STUDY OF TSH-CHECK-1 (THYRO-Check®) RAPIDTEST USING PRE-ASSAYED SERUM AND WHOLE BLOOD SAMPLES FOR THE DETERMINATION OF A POTENTIAL MATRIX EFFECT.

## I. Purpose

This study was performed to determine whether TSH-CHECK-1 rapid test (THYRO-Check®) shows potential matrix effect using a panel of TSH pre-assayed samples by reference methods (ROCHE Cobas 8000 and BIOMERIEUX VIDAS).

## II. Method

This study was performed on December 12<sup>th</sup>, 2017 using material indicated in Table 1.

Components	Lot
TSH-CHECK-1 Test (THYRO-Check®)	161028-027
Diluent	27107-02
TSH pre-assayed serum panel	071217

**Table 1: Components**

A panel of 105 TSH pre-assayed serum samples has been tested using TSH-CHECK-1 rapid test (THYRO-Check®).

At the same time, plasmas of negative TSH whole blood samples have been removed after centrifugation and replaced V/V by pre-assayed serums.

These samples have been tested using TSH-CHECK-1 qualitative test (THYRO-Check®) as per the procedure indicated in Table 2.

(Samples 1 to 60 using EDTA whole blood, and samples 22903758 to 24573626 using Citrated whole blood)

	Protocol
Sample	25 µL of serum or 50 µL of whole blood
Diluent	150 µL
Reading time	10 minutes

**Table 2: Protocol**

## III. Results

The results are indicated in Table 3.

Status	Sample	Gender	Age (years)	Origin	Method	TSH concentration (µUI/mL)	Results TSH-CHECK-1			
							Serum matrix		Whole blood matrix	
							Visual result	Interpretation	Visual result	Interpretation
Negative	22903758	M	54	FRANCE	Cobas	<0.01	-	-	-	-
	22903825	F	83	FRANCE	Cobas	0.13	-	-	-	-
	22903827	F	59	FRANCE	Cobas	<0.01	-	-	-	-
	22903891	F	60	FRANCE	Cobas	0.05	-	-	-	-
	22903967	F	56	FRANCE	Cobas	<0.01	-	-	-	-
	22903969	F	45	FRANCE	Cobas	<0.01	-	-	-	-
	22904036	M	54	FRANCE	Cobas	<0.01	-	-	-	-
	22904138	M	60	FRANCE	Cobas	<0.01	-	-	-	-
	22904145	F	64	FRANCE	Cobas	0.06	-	-	-	-
22904159	F	53	FRANCE	Cobas	0.12	-	-	-	-	

Status	Sample	Gender	Age (years)	Origin	Method	TSH concentration (µUI/mL)	Results TSH-CHECK-1			
							Serum matrix		Whole blood matrix	
							Visual result	Interpretation	Visual result	Interpretation
Negative	22904304	F	42	FRANCE	Cobas	0.17	-	-	-	-
	22904312	F	45	FRANCE	Cobas	0.05	-	-	-	-
	2	F	ns	FRANCE	Vidas	3.31	-	-	-	-
	3	F	ns	FRANCE	Vidas	2.65	-	-	-	-
	4	F	ns	FRANCE	Vidas	1.93	-	-	-	-
	5	F	ns	FRANCE	Vidas	1.1	-	-	-	-
	6	F	ns	FRANCE	Vidas	1.78	-	-	-	-
	8	F	ns	FRANCE	Vidas	2.98	-	-	-	-
	9	F	ns	FRANCE	Vidas	2.48	-	-	-	-
	10	F	ns	FRANCE	Vidas	1.78	-	-	-	-
	11	F	ns	FRANCE	Vidas	0.78	-	-	-	-
	12	F	ns	FRANCE	Vidas	1.96	-	-	-	-
	13	F	ns	FRANCE	Vidas	2.29	-	-	-	-
	<b>14</b>	<b>M</b>	<b>ns</b>	<b>FRANCE</b>	<b>Vidas</b>	<b>3</b>	<b>+/-</b>	<b>+</b>	<b>+/-</b>	<b>+</b>
	15	M	ns	FRANCE	Vidas	0.67	-	-	-	-
	16	M	ns	FRANCE	Vidas	1.93	-	-	-	-
	17	M	ns	FRANCE	Vidas	2.27	-	-	-	-
	18	M	ns	FRANCE	Vidas	2.42	-	-	-	-
	20	M	ns	FRANCE	Vidas	0.706	-	-	-	-
	21	M	ns	FRANCE	Vidas	1.361	-	-	-	-
	22	F	ns	FRANCE	Vidas	0.42	-	-	-	-
	23	F	ns	FRANCE	Vidas	1.91	-	-	-	-
	24	F	ns	FRANCE	Vidas	1.32	-	-	-	-
	25	M	ns	FRANCE	Vidas	0.6	-	-	-	-
	26	M	ns	FRANCE	Vidas	0.62	-	-	-	-
	27	M	ns	FRANCE	Vidas	2	-	-	-	-
	28	M	ns	FRANCE	Vidas	0.97	-	-	-	-
	29	M	ns	FRANCE	Vidas	3	-	-	-	-
	30	M	ns	FRANCE	Vidas	2.94	-	-	-	-
	31	M	71	FRANCE	Cobas	2.8	-	-	-	-
	Weak positive	<b>7</b>	<b>F</b>	<b>ns</b>	<b>FRANCE</b>	<b>Vidas</b>	<b>5.3</b>	<b>-</b>	<b>-</b>	<b>-</b>
1		F	ns	FRANCE	Vidas	6.32	+/-	+	+/-	+
22903970		F	90	FRANCE	Cobas	6.25	+/-	+	+/-	+
22903973		F	56	FRANCE	Cobas	6.05	+/-	+	+/-	+
22903975		F	66	FRANCE	Cobas	7.06	+/-	+	+/-	+
22904028		F	75	FRANCE	Cobas	9.20	+	+	+	+
22904031		F	52	FRANCE	Cobas	7.36	+	+	+/-	+
22904151		F	35	FRANCE	Cobas	9.87	+/-	+	+/-	+
22904384		F	81	FRANCE	Cobas	6.07	+/-	+	+/-	+
22904385		F	61	FRANCE	Cobas	9.50	+	+	+	+
22904388		M	67	FRANCE	Cobas	9.83	+/-	+	+/-	+
22904389		F	42	FRANCE	Cobas	8.30	+	+	+	+
22904460		M	84	FRANCE	Cobas	5.69	+	+	+/-	+
22904461		F	23	FRANCE	Cobas	5.95	+/-	+	+/-	+
22904466		M	70	FRANCE	Cobas	5.80	+/-	+	+/-	+

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							Serum matrix		Whole blood matrix	
							Visual result	Interpretation	Visual result	Interpretation
	22904512	F	90	FRANCE	Cobas	6.66	+	+	+	+
	22904547	M	88	FRANCE	Cobas	5.45	+/-	+	+/-	+
	22904549	F	72	FRANCE	Cobas	7.75	+/-	+	+/-	+
	22904575	F	52	FRANCE	Cobas	8.09	+	+	+	+
	22904580	F	70	FRANCE	Cobas	5.63	+/-	+	+/-	+
	22904684	M	32	FRANCE	Cobas	7.33	+	+	+	+
	22904690	M	68	FRANCE	Cobas	5.48	+/-	+	+/-	+
	32	F	94	FRANCE	Vidas	8.1	+/-	+	+/-	+
	33	F	88	FRANCE	Vidas	8.8	+/-	+	+/-	+
	34	M	71	FRANCE	Vidas	11.9	+/-	+	+/-	+
	35	F	26	FRANCE	Vidas	10.2	+/-	+	+/-	+
	36	F	76	FRANCE	Vidas	8.2	+	+	+	+
	37	F	85	FRANCE	Vidas	11.7	2+	+	2+	+
	38	M	82	FRANCE	Vidas	7.9	+	+	+	+
	39	F	83	FRANCE	Vidas	11.3	+	+	+/-	+
	40	F	53	FRANCE	Vidas	10.83	+	+	+	+
	41	M	94	FRANCE	Vidas	10.39	+	+	+	+
	42	M	80	FRANCE	Vidas	7.35	+	+	+/-	+
Strong positive	19	M	ns	FRANCE	Vidas	23.88	3+	+	3+	+
	23179547	M	71	FRANCE	Cobas	33.07	+/-	+	+/-	+
	23179554	M	71	FRANCE	Cobas	28.46	3+	+	2+	+
	23179628	F	85	FRANCE	Cobas	34.83	2+	+	2+	+
	23179640	F	88	FRANCE	Cobas	24.14	2+	+	2+	+
	23179642	F	83	FRANCE	Cobas	44.25	3+	+	2+	+
	23179673	F	94	FRANCE	Cobas	20.70	2+	+	2+	+
	23180343	F	76	FRANCE	Cobas	66.53	5+	+	4+	+
	24392514	F	53	FRANCE	Cobas	49.31	3+	+	3+	+
	24392593	M	85	FRANCE	Cobas	55.46	4+	+	4+	+
	24392938	M	82	FRANCE	Cobas	68.38	5+	+	3+	+
	24393329	M	94	FRANCE	Cobas	85.99	5+	+	4+	+
	24573390	F	26	FRANCE	Cobas	71.44	4+	+	4+	+
	24573626	M	80	FRANCE	Cobas	96.48	4+	+	4+	+
	43	M	80	FRANCE	Vidas	42.47	3+	+	3+	+
	44	M	80	FRANCE	Vidas	30.84	2+	+	2+	+
	45	M	94	FRANCE	Vidas	40.6	4+	+	4+	+
	46	M	94	FRANCE	Vidas	27.45	3+	+	3+	+
	47	F	26	FRANCE	Vidas	39.95	3+	+	2+	+
	48	F	26	FRANCE	Vidas	25.01	2+	+	2+	+
	49	M	82	FRANCE	Vidas	29.76	3+	+	3+	+
	50	M	82	FRANCE	Vidas	20.95	2+	+	2+	+
	51	F	76	FRANCE	Vidas	31.5	4+	+	3+	+
	52	F	76	FRANCE	Vidas	20.59	3+	+	3+	+
	53	F	53	FRANCE	Vidas	21.6	2+	+	2+	+
	54	F	83	FRANCE	Vidas	22.87	2+	+	2+	+
	55	M	80	FRANCE	Vidas	56.03	3+	+	3+	+

Status	Sample	Gender	Age (years)	Origin	Method	TSH concentration (µUI/mL)	Results TSH-CHECK-1			
							Serum matrix		Whole blood matrix	
							Visual result	Interpretation	Visual result	Interpretation
	56	M	94	FRANCE	Vidas	54.35	4+	+	3+	+
	57	M	85	FRANCE	Vidas	35.07	3+	+	3+	+
	58	M	85	FRANCE	Vidas	29.24	3+	+	2+	+
	59	M	85	FRANCE	Vidas	19.91	2+	+	2+	+
	60	M	80	FRANCE	Vidas	20.79	3+	+	3+	+

ns: no specified

**Table 3: Results obtained using a panel of TSH pre-assayed samples**

#### IV. Diagnostic specificity and sensitivity

The results are summarized in Table 4 (serum matrix) and Table 5 (Whole blood matrix).

TSH-CHECK-1 (THYRO-Check®)	Reference panel		
	-	+	Total
	-	39	1
+	1	64	65
Total	40	65	105

**Table 4: Results obtained with serum samples**

TSH-CHECK-1 (THYRO-Check®)	Reference panel		
	-	+	Total
	-	39	1
+	1	64	65
Total	40	65	105

**Table 5: Results obtained with whole blood samples**

**Diagnostic specificity:**  $(39/40) \times 100 = 97.5 \%$

**Diagnostic sensitivity:**  $(64/65) \times 100 = 98.46 \%$

**Overall correlation:**  $(39+64)/105 \times 100 = 98.1 \%$

#### V. Conclusion

This study shows that there is no difference of result interpretation between the results obtained with sera samples and those obtained with whole blood samples. Therefore, there is no matrix effect on TSH-CHECK-1 qualitative test (THYRO-Check®).

The diagnostic specificity, the diagnostic sensitivity and the overall correlation of TSH-CHECK-1 qualitative test (THYRO-Check®) are respectively of 97.5%, 98.46% and 98.1% compared with reference methods and using serum or whole blood samples.

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