

醫學檢驗部公告 (2020年2月)

一、公告定量檢驗項目之量測不確定度

依據 ISO15189 實驗室認證規範執行之。

- 1.量測不確定度(Uncertainty of Measurement, MU)：係指一量測結果的分散程度、可能誤差或可能存在的範圍區間。
- 2.依據 ISO15189 實驗室認證規範要求，實驗室應提供使用者量測不確定度之估計值，以幫助使用者評鑑檢驗可信度或影響報告結果。
- 3.生化及免疫分析項目於 2019 年 11 月變更檢驗設備，待收集半年之客觀品管數據，再行公告量測不確定度。其餘醫學檢驗部之定量檢驗項目之量測不確定度如附件。
- 4.範例：

實驗室 Glucose 之兩品管濃度平均值分別為 86 mg/dL 與 285 mg/dL，公告之量測不確定度估計值分別為 2.2% (1.9 mg/dL)及 2.4% (6.84 mg/dL)。若有病人空腹血糖數值為 129 mg/dL，則病人真正結果可能落在 127.1 – 130.9 mg/dL ($129 \pm 2.2\%$)之間；若有血糖數值為 328 mg/dL，病人真正結果可能落在 320.1 – 335.9 mg/dL ($328 \pm 2.4\%$)之間。

醫學檢驗部 定量檢驗量測不確定度一覽表(血液/血凝/一般檢驗)

公告日期：2020年2月

表單編號：EDCP-QP-0807/02

	檢驗項目	目標值	量測不 確定度	量測不確定 度估算值		檢驗項目	目標值	量測不 確定度	量測不確定 度估算值
1	WBC	3.1	4.6%	3~3.3	41	MONO%	12.8	16.4%	10.7~14.9
2	WBC	7.2	3.0%	7~7.4	42	MONO%	11.0	11.8%	9.7~12.3
3	WBC	16.5	2.2%	16.1~16.9	43	EO%	9.8	13.4%	8.5~11.1
4	RBC	2.4	1.6%	2.3~2.4	44	EO%	10.0	12.8%	8.7~11.3
5	RBC	4.4	1.4%	4.3~4.5	45	EO%	11.5	14.8%	9.8~13.2
6	RBC	5.3	1.2%	5.3~5.4	46	BASO%	4.8	8.0%	4.4~5.2
7	HGB	6.0	2.0%	5.9~6.1	47	BASO%	4.8	5.4%	4.5~5.1
8	HGB	11.9	1.2%	11.8~12	48	BASO%	4.8	5.0%	4.6~5
9	HGB	15.9	1.2%	15.7~16.1	49	NRBC#	0.1	14.2%	0.1~0.2
10	HCT	17.7	2.6%	17.2~18.2	50	NRBC#	0.4	9.0%	0.4~0.5
11	HCT	34.8	2.6%	33.9~35.7	51	NRBC#	1.1	7.2%	1~1.2
12	HCT	45.7	2.0%	44.8~46.6	52	MPV	8.4	5.2%	8~8.8
13	MCV	74.4	1.8%	73.1~75.7	53	MPV	10.2	2.4%	10~10.4
14	MCV	79.0	2.0%	77.4~80.6	54	MPV	10.0	1.8%	9.8~10.2
15	MCV	85.7	1.6%	84.3~87.1	55	PDW	6.3	7.2%	5.8~6.8
16	MCH	25.3	2.0%	24.8~25.8	56	PDW	9.6	4.0%	9.2~10
17	MCH	27.0	1.6%	26.6~27.4	57	PDW	9.7	3.0%	9.4~10
18	MCH	29.9	1.4%	29.5~30.3	58	PCT	0.1	15.4%	0.1~0.1
19	MCHC	34.2	2.6%	33.3~35.1	59	PCT	0.3	6.2%	0.2~0.3
20	MCHC	34.4	2.4%	33.6~35.2	60	PCT	0.6	4.2%	0.5~0.6
21	MCHC	35.0	1.8%	34.4~35.6	61	PT	10.9	1.9%	10.7~11.1
22	PLT	92.0	8.8%	83.9~100.1	62	PT	28.4	3.1%	27.5~29.3
23	PLT	256.0	4.2%	245.2~266.8	63	APTT	26.3	2.5%	25.6~27
24	PLT	568.0	3.4%	548.7~587.3	64	APTT	44.6	3.6%	43~46.2
25	RDW-SD	47.9	2.2%	46.8~49	65	Fibrinogen	246.6	15.6%	208.1~285.1
26	RDW-SD	46.1	2.2%	45.1~47.1	66	Fibrinogen	79.7	18.5%	64.9~94.5
27	RDW-SD	46.5	2.2%	45.5~47.5	67	D-Dimer	0.31	13.7%	0.3~0.4
28	RDW-CV	18.0	2.0%	17.6~18.4	68	D-Dimer	2.34	9.7%	2.1~2.6
29	RDW-CV	16.3	1.4%	16.1~16.5	69	FDP	8.26	15.8%	7~9.6
30	RDW-CV	15.1	1.4%	14.9~15.3	70	FDP	25.54	10.6%	22.8~28.2
31	RET%	5.0	6.4%	4.7~5.3	71	HbA1C	5.16	2.9%	5~5.3
32	RET%	2.0	8.2%	1.8~2.2	72	HbA1C	10.06	3.3%	9.7~10.4
33	RET%	0.8	12.6%	0.7~0.9	73	ESR	9	6.2%	8.4~9.6
34	NEUT%	39.2	4.8%	37.3~41.1	74	ESR	19	6.7%	17.7~20.3
35	NEUT%	41.4	4.4%	39.6~43.2	75	ESR	65	5.3%	61.6~68.4
36	NEUT%	47.1	3.6%	45.4~48.8	76	Microbilirubin	3.2	7.4%	3~3.4
37	LYMPH%	34.3	6.8%	32~36.6	77	Microbilirubin	17.7	6.8%	16.5~18.9
38	LYMPH%	31.1	6.8%	29~33.2	78	OB (EIA 定量)	73	7.6%	67.5~78.5
39	LYMPH%	25.9	5.6%	24.4~27.4	79	OB (EIA 定量)	144	6.2%	135.1~152.9
40	MONO%	12.0	19.0%	9.7~14.3	80	OB (EIA 定量)	617	5.0%	586.2~647.9

醫學檢驗部 定量檢驗量測不確定度一覽表(特殊檢驗/病毒量/血液氣體分析)

公告日期：2020年2月

表單編號：EDCP-QP-0807/02

	檢驗項目	目標值	量測不 確定度	量測不確定 度估算值		檢驗項目	目標值	量測不 確定度	量測不確定 度估算值
1	Anti Beta2-glycoprotein I	61.2	9.6%	55.3~67.1	41	FHHb	2	9	0~11
2	Anti Cardiolipin IgG	47.7	11.4%	42.3~53.1	42	FMetHb	11.71	0.96	10.8~12.7
3	Anti Cardiolipin IgM	54.5	7.6%	50.4~58.6	43	FMetHb	5.76	2.15	3.6~7.9
4	Anti CCP	43.6	18.2%	35.7~51.5	44	FMetHb	1.67	7.78	0~9.5
5	Anti dsDNA	43.0	19.2%	34.7~51.2	45	FO ₂ Hb	48.16	4.71	43.5~52.9
6	ENA-I SSA (Ro)	67.6	16.2%	56.7~78.6	46	FO ₂ Hb	75.46	0.54	74.9~76
7	ENA-I SSB (La)	31.5	20.8%	24.9~38.1	47	FO ₂ Hb	93.54	0.51	93~94.1
8	p-ANCA (MPS)	21.6	19.6%	17.3~25.8	48	K	3	4.00	2.88~3.12
9	c-ANCA (PRS)	11.5	16.0%	9.7~13.3	49	K	4.7	1.87	4.61~4.79
10	ENA-III Jo-1	36.2	10.6%	32.4~40	50	K	6.9	4.64	6.58~7.22
11	ENA-III Scl-70	110.6	14.8%	94.2~126.9	51	Na	122.6	1.81	120.4~124.8
12	ENA-II Sm	25.5	14.2%	21.9~29.1	52	Na	139.8	1.37	137.9~141.7
13	ENA-II RNP	41.5	17.4%	34.3~48.7	53	Na	159.8	1.04	158.1~161.5
14	Anti-CTD	11.5	15.6%	9.7~13.3	54	pCO ₂	64.7	3.4	62.5~66.9
15	單項過敏原 e1	2.8	11.8%	2.5~3.2	55	pCO ₂	42.7	2.4	41.7~43.7
16	單項過敏原 d1	25.3	12.0%	22.2~28.3	56	pCO ₂	25.7	3.2	24.9~26.5
17	IgE	25.0	8.4%	22.9~27.1	57	pH	7.213	0.2	7.199~7.227
18	IgE	113.5	8.0%	104.4~122.6	58	pH	7.433	0.2	7.418~7.448
19	IgE	414.5	8.4%	379.7~449.3	59	pH	7.574	0.2	7.559~7.589
20	AMH	2.4	10.6%	2.2~2.7	60	pO ₂	63.2	8.6	54.6~71.8
21	HBV viral load-High PC log (IU/mL)	6.3	3.0%	6.1~6.5	61	pO ₂	101.7	3.0	98.7~104.7
22	HBV viral load-Low PC log (IU/mL)	2.3	6.4%	2.2~2.4	62	pO ₂	153.1	2.4	150.7~155.5
23	HCV viral load-High PC log (IU/mL)	6.3	2.8%	6.1~6.5	63	tHb	7.3	4.4	7~7.6
24	HCV viral load-Low PC log (IU/mL)	2.3	11.4%	2~2.5	64	tHb	11.75	1.2	11.6~11.9
25	HIV viral load-High PC log (copies/mL)	5.4	4.6%	5.1~5.6	65	tHb	17.72	1.8	17.4~18
26	HIV viral load-Low PC log (copies/mL)	2.6	10.6%	2.3~2.9	66	Ketone	0.71	8.17	0.7~0.8
27	Osmolality	291.3	1	288.4~294.2	67	Ketone	4.39	5.97	4.1~4.7
28	Osmolality	550.9	2.62	536.4~565.4					
29	U-Osmolality	830.9	3	806~855.8					
30	Ca ²⁺	6.2	4.07	6~6.5					
31	Ca ²⁺	4.5	2.86	4.4~4.6					
32	Ca ²⁺	2.4	3.86	2.3~2.4					
33	Cl	86.8	2.4	84.7~88.9					
34	Cl	100.1	1.6	98.5~101.7					
35	Cl	119.7	1.6	117.8~121.6					
36	FCOHb	22.4	4.60	17.8~27					
37	FCOHb	10.6	1.76	8.8~12.3					
38	FCOHb	2.8	7.86	0~10.7					
39	FHHb	17.7	4.59	13.1~22.2					
40	FHHb	8.2	1.83	6.4~10					