

# Results of Japan Newborn Screening Proficiency Testing

## Neonatal Screening Centers in Taiwan

Survey No. : 2018Q1

### I. Routine Screening Items in Taiwan

#### Assay Item : TSH

Lab	Sample 801-1	Sample 801-2	Sample 801-3	Sample 801-4	Sample 801-5	Sample 801-6	Sample 801-7	Sample 801-8	Sample 801-9	Sample 801-10	Cut -Off	Unit	Method /Reagent
Lab1	-	-	19.29 (P)	-	-	-	-	-	-	-	9.0	μ U/ml	AutoDELFIA kit
Lab2	-	-	23.8 (P)	-	-	-	-	-	-	-	10	μ U/ml	AutoDELFIA kit
Lab3	-	-	20.4 (P)	-	-	-	-	-	-	-	10.0	μ U/ml	AutoDELFIA kit
Reference*	-	-	26.20 (P)	-	-	-	-	-	-	-	-	μ U/ml	-

\* The amount added by QA center.

\*\* The positive result assigned by the participants are indicated by red color in the table and the (P) indicates out-of-expected range (i.e. Positive) decision

#### Assay Item : 17-OHP

Lab	Sample 801-1	Sample 801-2	Sample 801-3	Sample 801-4	Sample 801-5	Sample 801-6	Sample 801-7	Sample 801-8	Sample 801-9	Sample 801-10	Cut -Off	Unit	Method /Reagent
Lab1	-	-	-	-	-	-	-	-	21.1 (P)	-	14.5	ng/ml	AutoDELFIA kit
Lab2	-	-	-	-	-	-	-	-	22.1 (P)	-	15	ng/ml	AutoDELFIA kit
Lab3	-	-	-	-	-	-	-	-	20.3 (P)	-	15.0	ng/ml	AutoDELFIA kit
Reference*	-	-	-	-	-	-	-	-	19.54 (P)	-	-	ng/ml	-

\* The amount added by QA center.

\*\* The positive result assigned by the participants are indicated by red color in the table and the (P) indicates out-of-expected range (i.e. Positive) decision

#### Assay Item : Gal

Lab	Sample 801-1	Sample 801-2	Sample 801-3	Sample 801-4	Sample 801-5	Sample 801-6	Sample 801-7	Sample 801-8	Sample 801-9	Sample 801-10	Cut -Off	Unit	Method /Reagent
Lab1	-	-	-	-	-	-	-	-	-	15.0 (P)	15.0	mg/dl	Enzymatic (fluorescent)
Lab2	-	-	-	-	-	-	-	-	-	23.1 (P)	8	mg/dl	Enzymatic (colorimetric)
Lab3	-	-	-	-	-	-	-	-	-	15.3 (P)	12.0	mg/dl	Enzymatic (fluorescent)
Reference*	-	-	-	-	-	-	-	-	-	16.44 (P)	-	mg/dl	-

\* The amount added by QA center.

\*\* The positive result assigned by the participants are indicated by red color in the table and the (P) indicates out-of-expected range (i.e. Positive) decision

### Assay Item : Phe

Lab	Sample 801-1	Sample 801-2	Sample 801-3	Sample 801-4	Sample 801-5	Sample 801-6	Sample 801-7	Sample 801-8	Sample 801-9	Sample 801-10	Cut -Off	Unit	Method /Reagent
Lab1	-	-	-	-	242.44 (P)	-	-	-	-	-	110	μM	MS/MS
Lab2	-	-	-	-	270.6 (P)	-	-	-	-	-	100	μM	MS/MS
Lab3	-	-	-	-	312.6 (P)	-	-	-	-	-	90	μM	MS/MS
Reference*	-	-	-	-	303.67 (P)	-	-	-	-	-	-	μM	-

\* The amount added by QA center.

\*\* The positive result assigned by the participants are indicated by red color in the table and the (P) indicates out-of-expected range (i.e. Positive) decision

### Assay Item : Met

Lab	Sample 801-1	Sample 801-2	Sample 801-3	Sample 801-4	Sample 801-5	Sample 801-6	Sample 801-7	Sample 801-8	Sample 801-9	Sample 801-10	Cut -Off	Unit	Method /Reagent
Lab1	-	-	-	94.22 (P)	-	-	-	-	-	-	46.6	μM	MS/MS
Lab2	-	-	-	100.8 (P)	-	-	-	-	-	-	50	μM	MS/MS
Lab3	-	-	-	130.7 (P)	-	-	-	-	-	-	60	μM	MS/MS
Reference*	-	-	-	127.66 (P)	-	-	-	-	-	-	-	μM	-

\* The amount added by QA center.

\*\* The positive result assigned by the participants are indicated by red color in the table and the (P) indicates out-of-expected range (i.e. Positive) decision

### Assay Item : Leu

Lab	Sample 801-1	Sample 801-2	Sample 801-3	Sample 801-4	Sample 801-5	Sample 801-6	Sample 801-7	Sample 801-8	Sample 801-9	Sample 801-10	Cut -Off	Unit	Method /Reagent
Lab1	-	-	-	-	-	-	-	-	-	-	250	μM	MS/MS
Lab2	-	-	-	-	-	-	-	-	-	-	280	μM	MS/MS
Lab3	-	-	-	-	-	-	-	-	-	-	280	μM	MS/MS
Reference*	-	-	-	-	-	-	-	-	-	-	-	μM	-

\* The amount added by QA center.

\*\* The positive result assigned by the participants are indicated by red color in the table and the (P) indicates out-of-expected range (i.e. Positive) decision

### Assay Item : Val

Lab	Sample 801-1	Sample 801-2	Sample 801-3	Sample 801-4	Sample 801-5	Sample 801-6	Sample 801-7	Sample 801-8	Sample 801-9	Sample 801-10	Cut -Off	Unit	Method /Reagent
Lab1	-	-	-	-	-	-	-	-	-	-	300	μM	MS/MS
Lab2	-	-	-	-	-	-	-	-	-	-	250	μM	MS/MS
Lab3	-	-	-	-	-	-	-	-	-	-	250	μM	MS/MS

Refer- ence*	-	-	-	-	-	-	-	-	-	-	-	-	μM	-
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\* The amount added by QA center.

\*\* The positive result assigned by the participants are indicated by red color in the table and the (P) indicates out-of-expected range (i.e. Positive) decision

### Assay Item : C3

Lab	Sample 801-1	Sample 801-2	Sample 801-3	Sample 801-4	Sample 801-5	Sample 801-6	Sample 801-7	Sample 801-8	Sample 801-9	Sample 801-10	Cut -Off	Unit	Method /Reagent
Lab1	-	-	-	-	-	-	8.25 (P)	-	-	-	4.74	μM	MS/MS
Lab2	-	-	-	-	-	-	9.523 (P)	-	-	-	5.5	μM	MS/MS
Lab3	-	-	-	-	-	-	8.59 (P)	-	-	-	6.00	μM	MS/MS
Refer- ence*	-	-	-	-	-	-	9.54 (P)	-	-	-	-	μM	-

\* The amount added by QA center.

\*\* The positive result assigned by the participants are indicated by red color in the table and the (P) indicates out-of-expected range (i.e. Positive) decision

### Assay Item : C5

Lab	Sample 801-1	Sample 801-2	Sample 801-3	Sample 801-4	Sample 801-5	Sample 801-6	Sample 801-7	Sample 801-8	Sample 801-9	Sample 801-10	Cut -Off	Unit	Method /Reagent
Lab1	-	1.22 (P)	-	-	-	-	-	-	-	-	0.57	μM	MS/MS
Lab2	-	1.305 (P)	-	-	-	-	-	-	-	-	0.52	μM	MS/MS
Lab3	-	1.81 (P)	-	-	-	-	-	-	-	-	0.60	μM	MS/MS
Refer- ence*	-	1.33 (P)	-	-	-	-	-	-	-	-	-	μM	-

\* The amount added by QA center.

\*\* The positive result assigned by the participants are indicated by red color in the table and the (P) indicates out-of-expected range (i.e. Positive) decision

### Assay Item : C5DC

Lab	Sample 801-1	Sample 801-2	Sample 801-3	Sample 801-4	Sample 801-5	Sample 801-6	Sample 801-7	Sample 801-8	Sample 801-9	Sample 801-10	Cut -Off	Unit	Method /Reagent
Lab1	-	-	-	-	-	-	-	-	-	-	0.27	μM	MS/MS
Lab2	-	-	-	-	-	-	-	-	-	-	0.35	μM	MS/MS
Lab3	-	-	-	-	-	-	-	-	-	-	0.30	μM	MS/MS
Refer- ence*	-	-	-	-	-	-	-	-	-	-	-	μM	-

\* The amount added by QA center.

\*\* The positive result assigned by the participants are indicated by red color in the table and the (P) indicates out-of-expected range (i.e. Positive) decision

### Assay Item : C8

Lab	Sample 801-1	Sample 801-2	Sample 801-3	Sample 801-4	Sample 801-5	Sample 801-6	Sample 801-7	Sample 801-8	Sample 801-9	Sample 801-10	Cut -Off	Unit	Method /Reagent
Lab1	-	-	-	-	-	-	-	-	-	-	0.56	μM	MS/MS

Lab2	-	-	-	-	-	-	-	-	-	-	-	0.50	$\mu$ M	MS/MS
Lab3	-	-	-	-	-	-	-	-	-	-	-	0.50	$\mu$ M	MS/MS
Reference*	-	-	-	-	-	-	-	-	-	-	-	-	$\mu$ M	-

\* The amount added by QA center.

\*\* The positive result assigned by the participants are indicated by red color in the table and the (P) indicates out-of-expected range (i.e. Positive) decision

## II. Pilot Screening Items in Taiwan

### Assay Item : Cit

Lab	Sample 801-1	Sample 801-2	Sample 801-3	Sample 801-4	Sample 801-5	Sample 801-6	Sample 801-7	Sample 801-8	Sample 801-9	Sample 801-10	Cut -Off	Unit	Method /Reagent
Lab1	-	-	-	-	-	-	-	-	-	-	29.0	$\mu$ M	MS/MS
Lab2	-	-	-	-	-	-	-	-	-	-	40	$\mu$ M	MS/MS
Lab3	-	-	-	-	-	-	-	-	-	-	40.0	$\mu$ M	MS/MS
Reference*	-	-	-	-	-	-	-	-	-	-	-	$\mu$ M	-

\* The amount added by QA center.

\*\* The positive result assigned by the participants are indicated by red color in the table and the (P) indicates out-of-expected range (i.e. Positive) decision

### Assay Item : C0/(C16+C18)

Lab	Sample 801-1	Sample 801-2	Sample 801-3	Sample 801-4	Sample 801-5	Sample 801-6	Sample 801-7	Sample 801-8	Sample 801-9	Sample 801-10	Cut -Off	Unit	Method /Reagent
Lab1	-	-	-	-	-	-	-	124.71 (P)	-	-	35.0	-	MS/MS
Lab2	-	-	-	-	-	-	-	134.4 (P)	-	-	-	-	MS/MS
Lab3	-	-	-	-	-	-	-	134.5 (P)	-	-	40.0	-	MS/MS
Reference*	-	-	-	-	-	-	-	106.75 (P)	-	-	-	-	-

\* The amount added by QA center.

\*\* The positive result assigned by the participants are indicated by red color in the table and the (P) indicates out-of-expected range (i.e. Positive) decision

### Assay Item : C5OH

Lab	Sample 801-1	Sample 801-2	Sample 801-3	Sample 801-4	Sample 801-5	Sample 801-6	Sample 801-7	Sample 801-8	Sample 801-9	Sample 801-10	Cut -Off	Unit	Method /Reagent
Lab1	-	-	-	-	-	-	-	-	-	-	0.78	$\mu$ M	MS/MS
Lab2	-	-	-	-	-	-	-	-	-	-	0.8	$\mu$ M	MS/MS
Lab3	-	-	-	-	-	-	-	-	-	-	0.75	$\mu$ M	MS/MS
Reference*	-	-	-	-	-	-	-	-	-	-	-	$\mu$ M	-

\* The amount added by QA center.

\*\* The positive result assigned by the participants are indicated by red color in the table and the (P) indicates out-of-expected range (i.e. Positive) decision

**Assay Item : C14 : 1**

Lab	Sample 801-1	Sample 801-2	Sample 801-3	Sample 801-4	Sample 801-5	Sample 801-6	Sample 801-7	Sample 801-8	Sample 801-9	Sample 801-10	Cut -Off	Unit	Method /Reagent
Lab1	-	-	-	-	-	-	-	-	-	-	0.44	μM	MS/MS
Lab2	-	-	-	-	-	-	-	-	-	-	0.8	μM	MS/MS
Lab3	-	-	-	-	-	-	-	-	-	-	0.80	μM	MS/MS
Reference*	-	-	-	-	-	-	-	-	-	-	-	μM	-

\* The amount added by QA center.

\*\* The positive result assigned by the participants are indicated by red color in the table and the (P) indicates out-of-expected range (i.e. Positive) decision

**Assay Item : C14 : 1/C2**

Lab	Sample 801-1	Sample 801-2	Sample 801-3	Sample 801-4	Sample 801-5	Sample 801-6	Sample 801-7	Sample 801-8	Sample 801-9	Sample 801-10	Cut -Off	Unit	Method /Reagent
Lab1	-	-	-	-	-	-	-	-	-	-	-	μM	MS/MS
Lab2	-	-	-	-	-	-	-	-	-	-	-	μM	MS/MS
Lab3	-	-	-	-	-	-	-	-	-	-	-	μM	MS/MS
Reference*	-	-	-	-	-	-	-	-	-	-	-	μM	-

\* The amount added by QA center.

\*\* The positive result assigned by the participants are indicated by red color in the table and the (P) indicates out-of-expected range (i.e. Positive) decision

**Assay Item : C16OH**

Lab	Sample 801-1	Sample 801-2	Sample 801-3	Sample 801-4	Sample 801-5	Sample 801-6	Sample 801-7	Sample 801-8	Sample 801-9	Sample 801-10	Cut -Off	Unit	Method /Reagent
Lab1	0.20 (P)	-	-	-	-	-	-	-	-	-	0.18	μM	MS/MS
Lab2	0.374 (P)	-	-	-	-	-	-	-	-	-	0.15	μM	MS/MS
Lab3	-	-	-	-	-	-	-	-	-	-	0.25	μM	MS/MS
Reference*	0.17 (P)	-	-	-	-	-	-	-	-	-	-	μM	-

\* The amount added by QA center.

\*\* The positive result assigned by the participants are indicated by red color in the table and the (P) indicates out-of-expected range (i.e. Positive) decision

**Assay Item : C18OH**

Lab	Sample 801-1	Sample 801-2	Sample 801-3	Sample 801-4	Sample 801-5	Sample 801-6	Sample 801-7	Sample 801-8	Sample 801-9	Sample 801-10	Cut -Off	Unit	Method /Reagent
Lab1	-	-	-	-	-	-	-	-	-	-	0.25	μM	MS/MS
Lab2	-	-	-	-	-	-	-	-	-	-	0.5	μM	MS/MS
Lab3	-	-	-	-	-	-	-	-	-	-	0.20	μM	MS/MS
Reference*	-	-	-	-	-	-	-	-	-	-	-	μM	-

\* The amount added by QA center.

\*\* The positive result assigned by the participants are indicated by red color in the table and the (P) indicates out-of-expected range (i.e. Positive) decision

### III. Other

#### Assay Item : C3/C2

Lab	Sample 801-1	Sample 801-2	Sample 801-3	Sample 801-4	Sample 801-5	Sample 801-6	Sample 801-7	Sample 801-8	Sample 801-9	Sample 801-10	Cut -Off	Unit	Method /Reagent
Lab1	-	-	-	-	-	-	0.89 (P)	-	-	-	0.26	-	MS/MS
Lab2	-	-	-	-	-	-	-	-	-	-	-	-	MS/MS
Lab3	-	-	-	-	-	-	-	-	-	-	-	-	MS/MS
Reference*	-	-	-	-	-	-	0.83 (P)	-	-	-	-	-	-

\* The amount added by QA center.

\*\* The positive result assigned by the participants are indicated by red color in the table and the (P) indicates out-of-expected range (i.e. Positive) decision

#### Assay Item : C18 : 1OH

Lab	Sample 801-1	Sample 801-2	Sample 801-3	Sample 801-4	Sample 801-5	Sample 801-6	Sample 801-7	Sample 801-8	Sample 801-9	Sample 801-10	Cut -Off	Unit	Method /Reagent
Lab1	0.27 (P)	-	-	-	-	-	-	-	-	-	0.16	$\mu$ M	MS/MS
Lab2	0.325 (P)	-	-	-	-	-	-	-	-	-	0.15	$\mu$ M	MS/MS
Lab3	0.24 (P)	-	-	-	-	-	-	-	-	-	0.20	$\mu$ M	MS/MS
Reference*	0.17 (P)	-	-	-	-	-	-	-	-	-	-	$\mu$ M	-

\* The amount added by QA center.

\*\* The positive result assigned by the participants are indicated by red color in the table and the (P) indicates out-of-expected range (i.e. Positive) decision

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若有任何疑問,歡迎來電(函)聯繫或指教



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