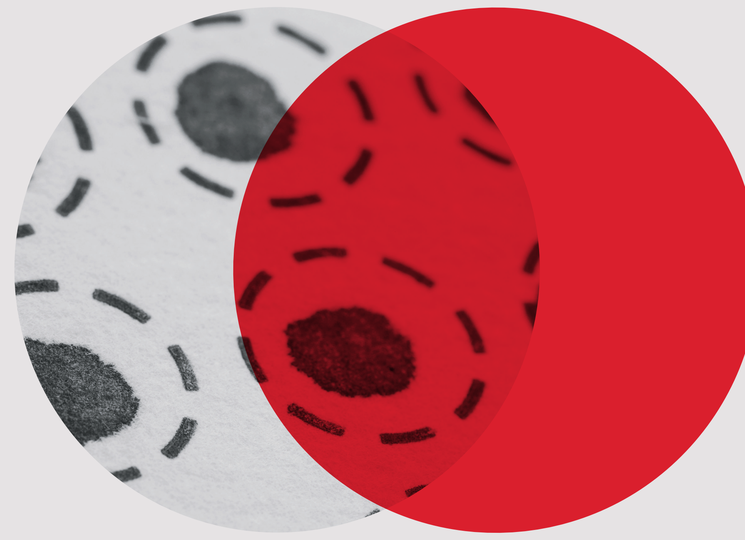
Development of an Inborn Errors Dried Blood Spot External Quality Assurance Program



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Introduction

The limited availability of Centres for Disease Control Dried Blood Spot (DBS) external quality assurance (EQA) material for non-US participants and quarantine regulations, prompted the development of an Asia-Pacific DBS-EQA program.

The RCPAQAP in conjunction with the Australasian Association of Clinical Biochemists (AACB) Inborn Errors Advisory Committee designed a program to fulfil local needs in the Asia-pacific region.

Method

The material provided was a dried blood spot consisting of a 75uL volume of whole blood on Whatman filter paper. Participants were provided with two dried blood spots per sample for analysis. The whole blood sample was spiked to achieve 6 linearly related analytes to accommodate a program of 6 surveys a year with two samples per survey.

The analytes included in the 2019 program were thyroid stimulating hormone (TSH), immunoreactive trypsinogen (IRT), tyrosine (tyr), phenylalanine (phe) and 17 hydroxy progesterone (17OHP).

The analytical performance specifications (APS) were initially set at +/-10% and the central values were derived from the all result medians and compared with the expected values from the spiking protocol.

Results

A total of 5 Australian laboratories enrolled in the program in February 2019. 4 laboratories returned results for the low (Level 1) and High (Level 6) samples, respective medians were as follows: TSH (1.0-350mIU/L) and IRT (8-220ug/L). 2 laboratories returned results for 17-OHP (5.0-150nmol/L). 5 laboratories returned results for Phenylalanine (20-2020ug/L) and tyrosine (35-1600ug/L). The initial results showed linearity for TSH, IRT, Phe and Tyrosine with greater than 80% of laboratories returning results within the APS for those analytes. This confirms the validity of the performance limits.

Figure 1. All laboratory medians and measure of dispersion represented as box-whisker plots for the 6 levels of the RCPAQAP blood spot program. (17OHP not displayed as two distinct method principles are used by participants i.e. immunoassay and mass spectrometry)

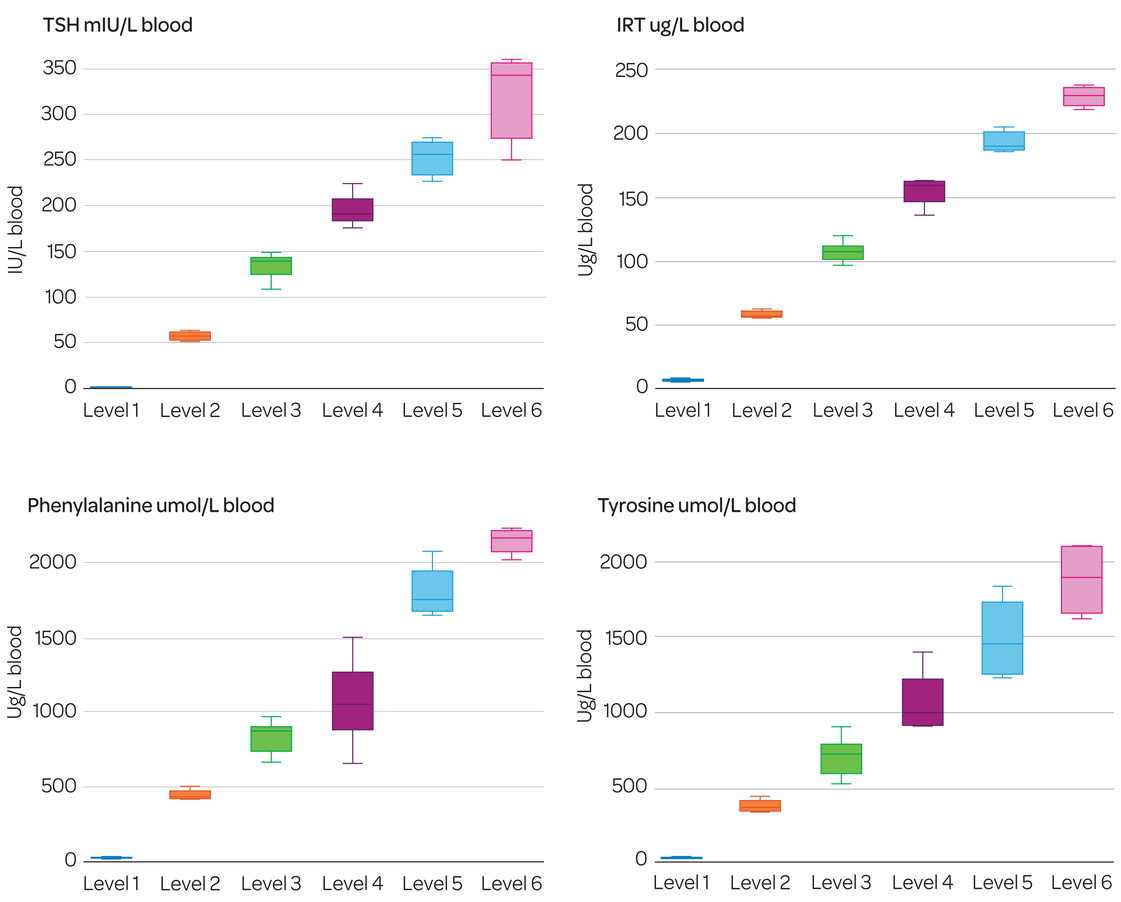
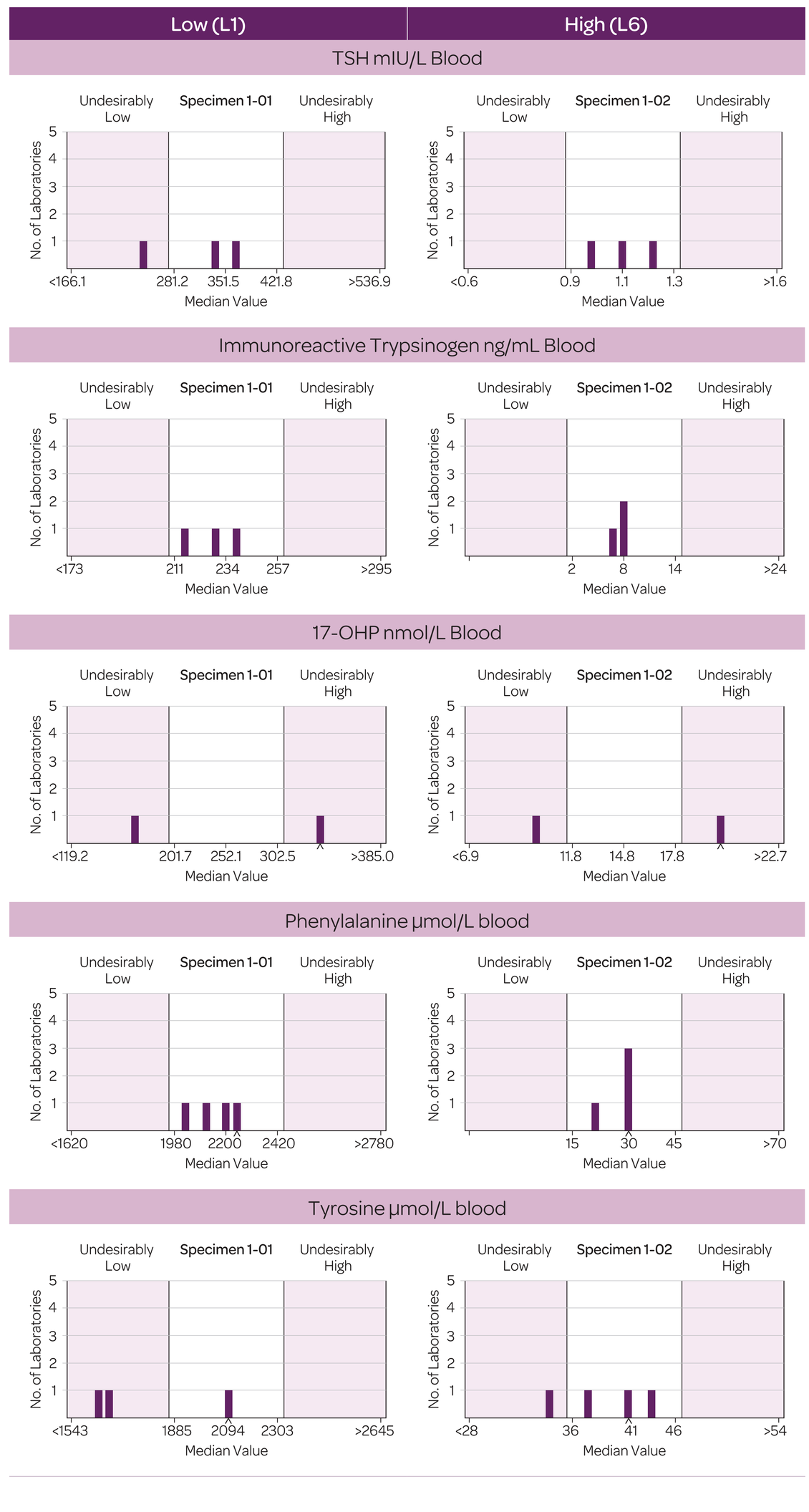


Table 1. Target Concentration range for low and high concentration levels.

Measureand	Low (L1)	High (L6)
TSH	5 mIU/L blood	250 mIU/L blood
IRT	10 ng/mL blood	250 ng/mL blood
17OHP	10 nmol/L blood	150 nmol/L blood
Phenylalanine	20 µmol/L blood	2000 µmol/L blood
Tyrosine	10 µmol/L blood	250 µmol/L blood

Figure 2. All Laboratory histograms for levels 1 and 6 of each of the five analytes.



Conclusion

Although only a small number of laboratories participated in the 2019 program, the results indicate that most users perform within the analytical performance specifications for their method and a linear material was achieved. We have successfully established a DBS-EQA program for the Asia-Pacific region. Future developments include analyte expansion and clinical case interpretation.

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