SpOtOn Clinical Diagnostics

SCD001

Newborn dried blood spot haemoglobinopathy screening using electrospray mass spectrometry-mass spectrometry (MSMS)

WARNING:
SpOtOn Clinical Diagnostics strongly recommends that the user contacts SpOtOn before first use of SCD001 for advice on equipment to be used and tips on using the test.

STORAGE

Kits should be stored at or below -70 °C until required for use. Individual reagent vials should only be thawed on the day of use, do not re-freeze

ASSAY PROCEDURE

Dried blood spots (3mm) should be punched into polypropylene 96 deep well plates

Each reagent vial contains sufficient reagent for two polypropylene 96 deep well plates containing DBS

Working reagents should be used within 2h following preparation, or according to a locally validated protocol

1. Thaw reagent 1 (vial **Reagent 1**), modified stable isotope labeled sickle T1 peptide, and reagent 2 (vial **Reagent 2**), TPCK treated trypsin.

2. Working **Reagent 1** reagent. Dilute the complete contents of **Reagent 1** in 12mL of deionised water, taking care to ensure complete mixing.

3. Working **Reagent 2** reagent. Dilute the complete contents of **Reagent 2** in 12mL of deionised water, again taking care to ensure complete mixing.

4. Using an 8 channel manual pipettor, (automated pipetting stations can be used but will require local validation) add 50µL of working reagent **Reagent 1**, using a reverse pipetting technique, to each well containing a DBS.

5. Mix the plate gently using lateral movement. Ensure that the DBS are immersed in the liquid.

6. Using an 8 channel manual pipettor, (automated pipetting stations can be used but will require local validation) add 50µL of working reagent **Reagent 2**, using a reverse pipetting technique, to each well containing a DBS and an aliquot of working reagent **Reagent 1**.

7. Mix the plate gently using lateral movement. Ensure that the DBS are immersed in the liquid. Seal with a specified sealing cap.

8. If possible, centrifuge the plate in a low speed centrifuge with suitable 96well plate carriers (1500g, 2min) to ensure that the liquids and DBS are collected at the bottom of the well.

9. Incubate the plate at 37°C for 30-45 min with gentle shaking.

10. After incubation, remove the plate from the incubator, remove the sealing cap, and carefully, to avoid splashing, add 1 mL of stopping solvent (acetonitrile:water, 90:10 with 0.025% formic acid) to each well using an Eppendorf repeating dispenser, or equivalent.

11. Reseal, making sure the position is the same as during incubation, and mix the plate gently using lateral movement.

12. Place the sealed plate into the autosampler for MSMS analysis.

Safety Information

Reagent 1 includes <1% w/v modified stable isotope labeled sickle T1 peptide. This substance is not a hazardous substance or mixture neither is it classified as dangerous according to Regulation (EC) No. 1272/2008.

Reagent 2 includes <1% w/v TPCK treated trypsin.
Trypsin may cause eye irritation or skin irritation. Use appropriate personal protective equipment (gloves, eye protection).
In case of skin contact Wash off with soap and plenty of water and consult a physician. **In case of eye contact** Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.

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