The Laboratory Services Reform Programme

ADVICE NOTE

Sweat Chloride Testing:

Harmonisation of Decision Levels

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Clinical Practice Guidance Document Cover Sheet

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The Laboratory Services Reform Programme offers the following advice:

1 Advice for Laboratory Users

1. In considering the sweat test chloride result the cut-off recommended by the Cystic Fibrosis Foundation Consensus Guidelines (2017), endorsed by the European Cystic Fibrosis Society, should be applied for both children and adults:
    a. Less than (<) 30 mmol/L
    A sweat chloride concentration of less than 30 mmol/L makes a diagnosis of cystic fibrosis unlikely.

    b. 30-59 mmol/L
    A sweat chloride concentration of 30-59 mmol/L is an intermediate result, which requires further cystic fibrosis assessment

    c. Equal to or greater than (≥) 60 mmol/L
    A sweat chloride concentration of 60 mmol/L or above supports the diagnosis of cystic fibrosis

2. The Cystic Fibrosis Consultants throughout Ireland and the National Clinical Programme for Cystic Fibrosis have reviewed and accepted this change to the sweat chloride categories

2 Advice for Laboratories

3. We recommend that all clinical laboratories conducting sweat tests update the sweat test chloride lower limit cut-off to that from the Cystic Fibrosis Foundation Consensus Guidelines (2017), endorsed now by the European Cystic Fibrosis Society and the HSE National Programme for Cystic Fibrosis.

4. The sweat chloride diagnostic level below which CF is considered unlikely has been revised to less than 30 mmol/L for all ages. Previously, the lower limit had been less than 40 mmol/L if aged over 6 months and less than 30 mmol/L if aged less than 6 months.

5. The updated cut-offs along with suggested comments are shown above.

3 Background

A consensus guideline has been published by the Cystic Fibrosis Foundation[1] and endorsed by the European Cystic Fibrosis Society[2]. The purpose is to improve diagnosis and achieve standardised definitions worldwide. Updated Sweat Chloride Decision Levels, to be applied for both adults and children are set. Harmonising these decision levels nationally will facilitate consistency of results reporting around the country.

Updated Sweat Chloride Decision Levels (Children and Adults)	
Less than (<) 30 mmol/L	A sweat chloride concentration of less than 30 mmol/L makes a diagnosis of cystic fibrosis unlikely.
30-59 mmol/L	A sweat chloride concentration of 30-59 mmol/L is an intermediate result which requires further cystic fibrosis assessment
Equal to or greater than (≥) 60 mmol/L	A sweat chloride concentration of 60 mmol/L or above supports the diagnosis of cystic fibrosis

While a sweat chloride concentration of less than 30 mmol/L makes a diagnosis of cystic fibrosis unlikely rare cases have been described. Where clinical suspicion remains repeat or further investigation may be considered.

4 References

1. Farrell, P. M., et al. (2017). Diagnosis of Cystic Fibrosis: Consensus Guidelines from the Cystic Fibrosis Foundation. The Journal of Pediatrics, 181, S4–S15.e1. https://doi.org/10.1016/j.jpeds.2016.09.064

2. Cirilli, N., et al., on behalf of the European Cystic Fibrosis Society (ECFS) Diagnostic Network Working Group (2022). Standards of care guidance for sweat testing; phase two of the ECFS quality improvement programme. Journal of Cystic Fibrosis, 21, 434-441. https://doi.org/10.1016/j.jcf.2022.01.004

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