

# International External Quality Evaluation on IESweat II, a point of care sweat test analyzer



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## Introduction

The concentration of chloride in sweat remains the gold standard for confirming the diagnosis of Cystic Fibrosis. The sweat test is a tedious laboratory test that traditionally requires 3 correlative steps: stimulation, collection and analysis. A new sweat chloride analyzer that allows the direct determination of chloride in sweat using disposable cards could reduce the handling of samples and facilitate the sweat test at point of care.

## Objectives

To compare the analytical performance of the new IESweat II sweat chloride analyzer (TECIL, SA, 08005 Barcelona, Spain) with traditional laboratory methods through participation in an international program of external quality assessment.

## Methods and materials

The chloride of 24 blind samples with disposable sensor cards on the IESweat II sweat chloride analyzer (RIQAS sweat testing program from Randox Laboratories, Ltd) was evaluated monthly during 2 years.

## Results

The results of the IESweat II analyzer were compared with 41 laboratories, using 5 different chloride determination methods (Coulometry, Colorimetry, Titrimetry, Direct ISE Potentiometry, Indirect ISE Potentiometry) from 15 countries belonging to 3 continents. The cycle average absolute SDI for cycle1 was 1,02 and 0,46 for cycle 1 and 2 respectively. Methods with SDI values below 2 are classified as "acceptable performance".

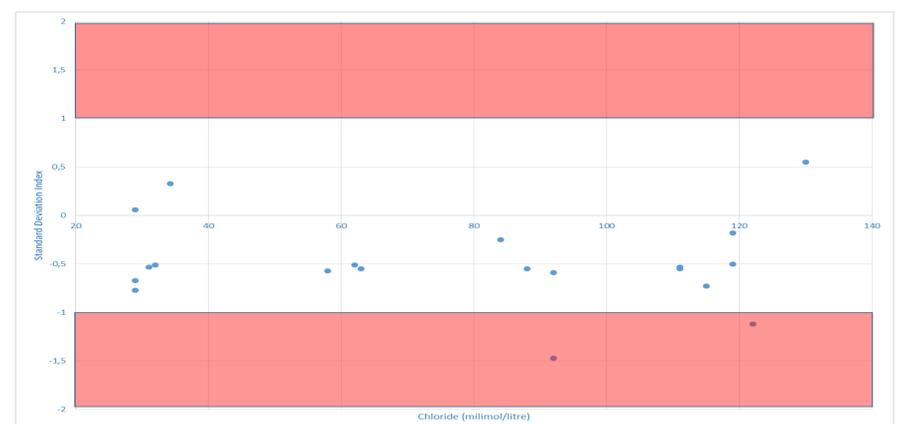


Fig 1: Standard Deviation Index (SDI) vs chloride concentration

Also, looking on the number of samples per method, during first 12 samples, most of the samples were analyzed using coulometric and titrimetric methods being ion selective electrode the least method used, on the other hand, during the second year the number of samples analyzed diminished but this time the number of samples analyzed by titrimetry were almost equal as ion selective electrode methods, being coulometric method the most used during this second year.

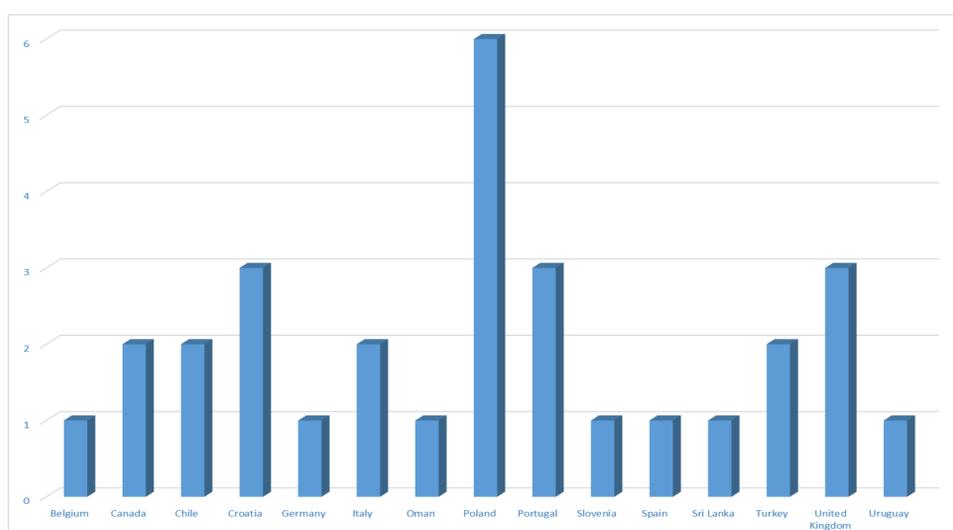


Fig.2: Participation by countries

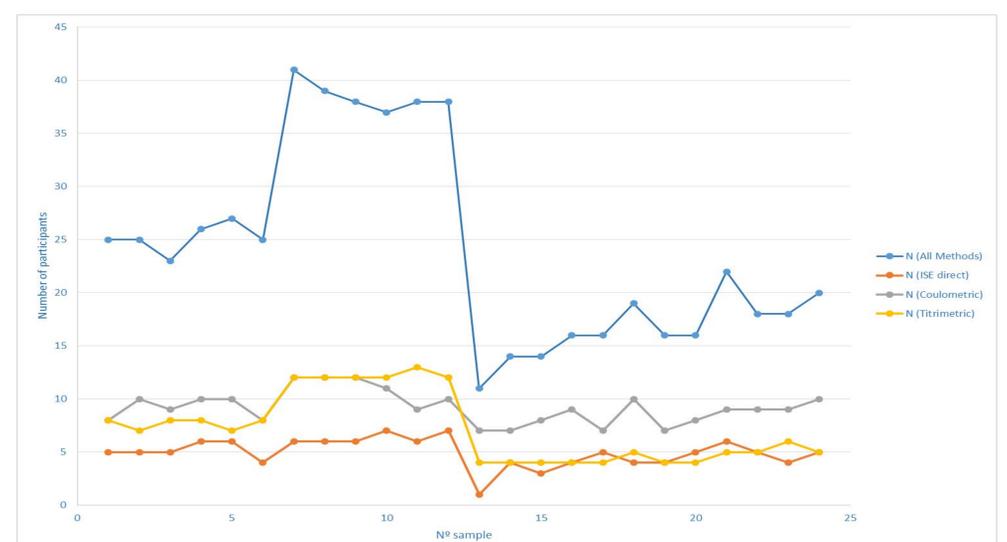


Fig 3: Participation by methods

## Conclusion

The analytical performance of IESweat is comparable to that of conventional laboratory analytical methods for analyzing chloride in sweat. The results obtained confirm the validity of the new IESweat II sweat chloride analyzer as an alternative to traditional laboratory methods approved in the current guidelines for the diagnosis of cystic fibrosis.