

Comparative study: evaluation of accuracy of ASO measurement with the POC instrument Eurolyser CUBE

Antistreptolysin O (ASO) is an antibody produced by the human body against the foreign toxin streptolysin O (SLO), which itself is produced by streptococcus Class A bacteria (Streptococcus pyogenes). Streptococcus Group A (Streptococcus pyogenes) is a bacterium that causes strep throat infections and numerous other infections. ASO is the most common of several antibodies present in the immune system in response to infections with streptococcus Group A. An ASO point-of-care quick test is a simple test for diagnosing a possible infection directly in the doctor's office - in a matter of minutes.

The aim of this comparative study was to evaluate the accuracy of ASO measurement with a Eurolyser CUBE analyser and to compare the results with those from other standard laboratory testing methods.

Antistreptolysin O, commonly abbreviated ASO or ASLO, is an antibody that is present in human blood during streptococcal infections, released by the body against the foreign toxin streptolysin O (SLO). A quantitative ASO blood test detects the amount of antibodies produced as a response to streptococcal infection. However, the result of such a quick test – the patient's ASO value – does not indicate a specific disease, but rather determine the level of antibodies and illustrate the reaction in the patient's body, f. e. how weakened the immune system may already be. A healthy, functioning human immune system should be able to properly regulate the ASO amount it needs to neutralize formed streptolysin.

If the results indicate a high level of ASO in the patient's blood this is signal a dangerous amount of antibodies is present in the patient's body. While these antibodies do attack the streptococcus, they can also tear down the body's own tissue that has a similar antigenic structure as streptococcus: the cardiac muscle, the kidney, synovial joints etc.

If an appropriate antibiotics therapy is commenced in time, the production of streptolysin by the streptococcus can be prevented. Streptolysin has an adverse effect on red blood cells and other important cells of human body, as it attacks the cytoplasmic membrane and sticks to its surface via a strong link.

However, if a patient consults their doctor too late, or the streptococcus is not diagnosed straightaway, a serious problem can occur: even if the doctor prescribes the right antibiotics it hardly stops or slow down the overproduction of antibodies. Subsequently, an extended period of antibiotic treatment is required during which the patient's ASO level may not decrease at all for a long time. For antibiotics to adequately perform it is essential to discover/diagnose streptococcus in time!

Doctors should monitor the ASO level of affected patients, because after an acute streptococcal disease has been treated, the therapy should focus on discovering the underlying cause; a properly functioning immune system should not form copious amounts ASO antibodies at all – rather should its receptors be able to detect and destroy streptococci themselves.

Options of streptococci A diagnoses

Bacterial infections of the upper respiratory tract represent a health threat whose diagnosis is one of the most common challenges for doctors, especially for surgeons and pediatricians. The earlier a diagnosis is made and the appropriate therapy can be initiated, the lower the risk for complications such as rheumatic fever and post-streptococcal glomerulonephritis.

In case of suspected streptococcal inflammation of the upper respiratory tract, the common practice is to take throat swab, send it to a laboratory for microbiological examination and get the results of in a matter of roughly two days. Depending on the ASO level of the patient, an antibiotic therapy is subsequently commenced.

Another, faster method for doctors to diagnose beta-hemolytic streptococcus are rapid tests in strips or cassettes, e.g. immunoassay Strep A. Using a special spawning sticks for the throat swab, qualitative results (infection: yes/no?) are available in approximately in six minutes. In case of a positive rapid test result, the doctor takes a blood sample and sends it to a lab. There an ASO test is performed, the result of which is available usually a day later.

For both methods, it takes 1-2 days for the doctor to know the factual condition of the patient.

Today, however, offers the possibility to check health condition of the patient (streptococcal attack of organism) in the doctor's office with help of very simple test. It is an immediate examination of values ASO from one drop of capillary blood directly in the doctor's office on the POCT Eurolyser CUBE instruments, whose accuracy of measurements were compared in the described comparative study.



The point-of-care instrument Eurolyser CUBE is a versatile analyser which can now run an ASO test

Comparison of results ASLO levels

This study compared the results ASO level values of 45 patients, which were suspected on streptococcal infection. Measurements carried out on POCT device Eurolyser CUBE. In the doctor's office there was collected a drop of capillary blood and immediately tested in the office on this instrument. From all patients was simultaneously collected venous blood samples, which were sent

to biochemical laboratory for ASO analysis by verified diagnostic test kit SENTINEL ASO on a laboratory analyzer Architect C8000, Abbott.

The results of measuring the value of the number of ASO Eurolyser CUBE unit and laboratory analyzer Architect C8000 were compared between themselves. Based on this comparison quality was evaluated by measuring values ASO device CUBE as fully compliant.

Evaluation of qualitative results of ASO

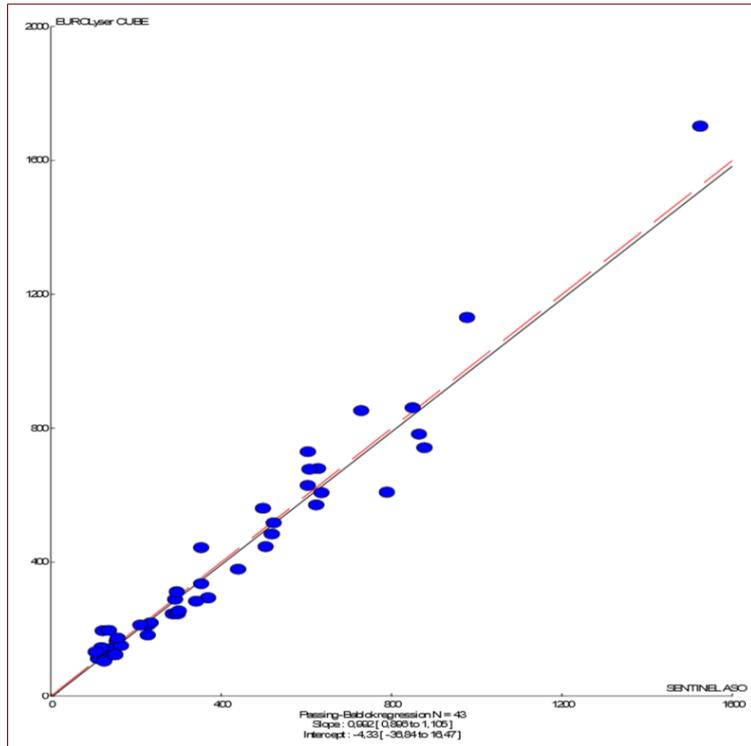
The measured values of ASO, interpreted using cut-off, corresponding to the analytical procedures, so as a qualitative result, to both devices match in 97.78 percent of cases, the disagreement was 2.22 percent. (Specifically, one mismatch from 45 matches, in addition, just in a "gray zone" on the boundary surface ASO equal to the value of common cut off = 200 IU /ml ,when both quantitative results differed by only 10 percent from 200 IU/ml).

Graph No.2 Linear regression analysis

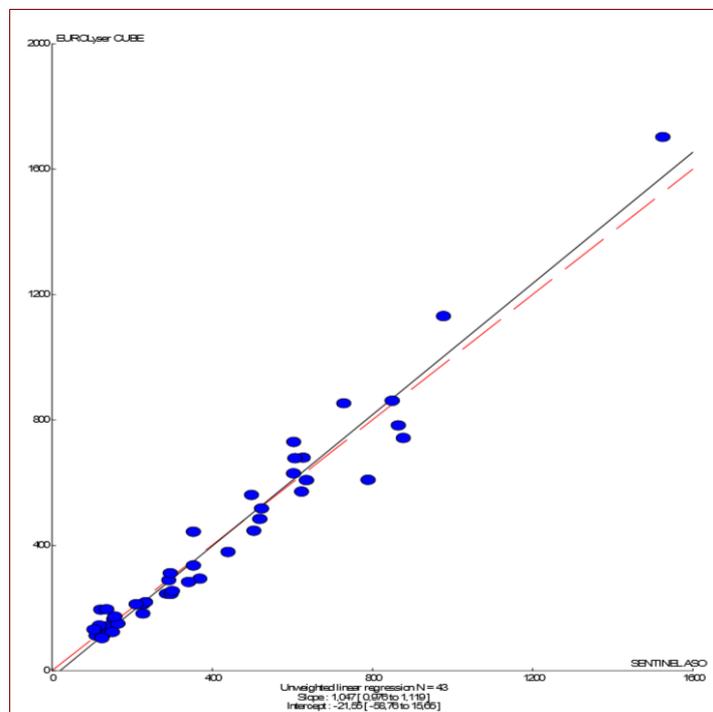
Comparison of quantitative results ASO levels

ASO levels measured during the comparative study were among the abovementioned qualitative aspects evaluated also mathematically – with correlation / regression analysis, including graphic interpretation. The results are shown in the following graphs. Graphs 1, 2 and 3 present regression analysis Passig Bablock, linear regression analysis and Deming's regression analysis.

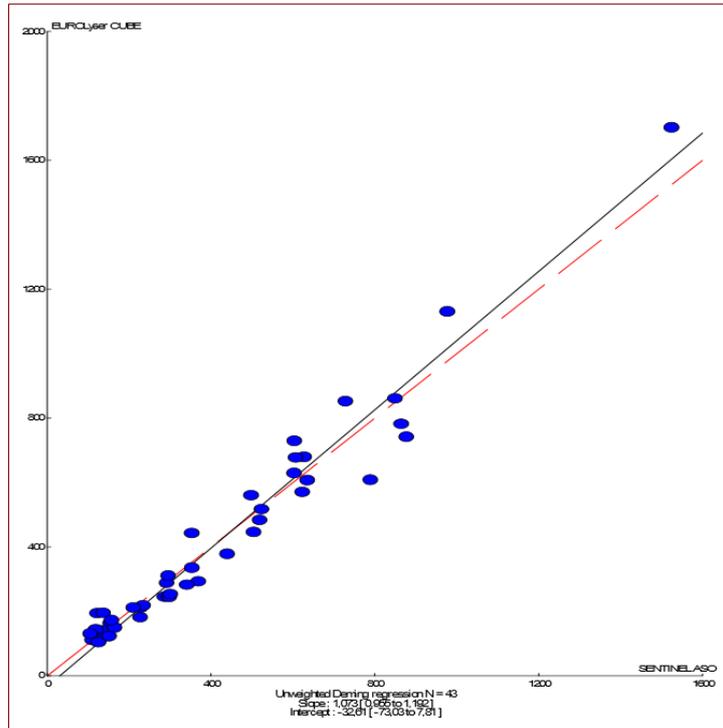
In all cases they show the measured data obtained from the test CUBE device and data of the reference method - Sentinel / Architect close dependence documented with graph, quantified with parameters of the equation of the regression line and correlation coefficient.



GRAPH 1: Passig Bablock Regressionsanalyse

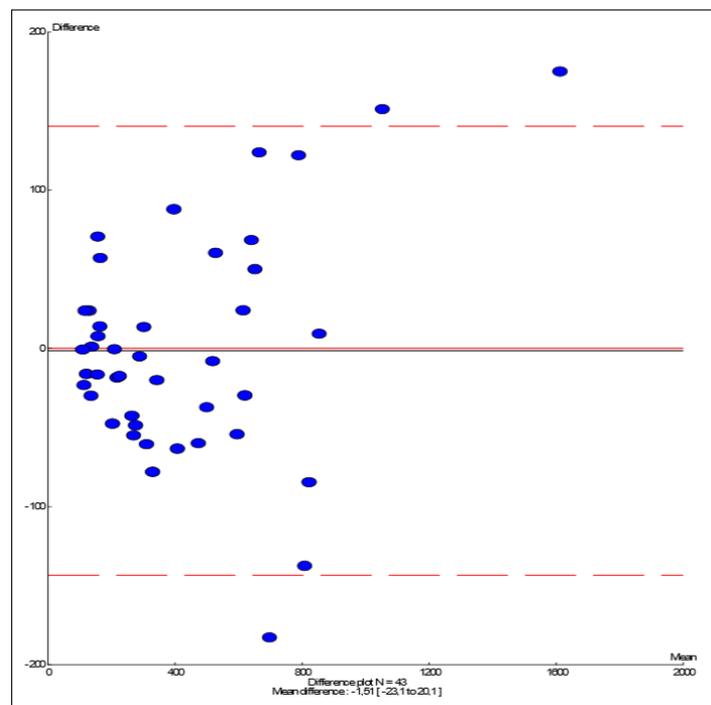


GRAPH 2: Ungewichtete Regressionsanalyse



GRAPH 3: Deming's regression analyse

Die Gesamtergebnisse und einen Überblick über die Messungen zeigt Graph 4.



GRAPH 4: Differentialanalyse

CUBE is a reliable analyzer

The aim of this comparative study was to verify in praxis, that POCT analyzer Eurolyser CUBE will find its practical use in the offices of pediatrics and general practitioners not only for the measurement of CRP values, PT (INR), HbA1c, hsCRP and Cystatin C (GFR), but also for determination of ASO values. These data are for doctor important in the moment, when the patient had streptococcal infection or when his body is just struggling with this infection.

Graph No. 4 Differential chart

Comparison of results clearly demonstrated, that the ASO values measured by the monitored patients on POCT devices Eurolyser CUBE are consistent with the values if the same blood sample measured in the laboratory.

POCT analyzer CUBE therefore represents for doctors an ideal way, how thanks to the ASO test get immediately quantitative result in his office, how to maximally short the diagnostic process, thanks which has a better view about the presence of bacterial infection of the organism, followed by immediately initiation of appropriate treatment. This process is in effect appreciated especially by the patient.

Added the ASO to the device CUBE (or an older version of it called SMART) is whenever possible, without any additional investment.

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