August 2026

Report guidance for ”HIL-index and interference” no. 4131 DK

General for all rounds

Purpose

The program consists of two types of rounds named the original rounds and the index-targeted rounds. In general, for all rounds the object of this program is to examine the actual determination of hemolysis (H), icterus (I) and lipemia (L) known as the HIL-index in the samples. Is it possible to compare the determination of the HIL-index between the instrument groups?
Moreover, the object of the original rounds is to examine the interference caused by elevated either H-, I- or L-index. This is done by comparison of the analysis results of the up to 7 components between the two different samples, the normal sample A and sample B, which is the same as sample A, except for added hemoglobin, bilirubin or Intralipid.

About interference

Interference can occur in several ways. In all cases, the measured value of a component is changed as a result of interference from H, I or L such that the component is measured falsely too high or falsely too low.
In the case of hemolytic interference, the concentration of a given component may be higher in the erythrocytes, which is why the concentration of this component will be falsely increased in the plasma when the erythrocytes hemolyze (e.g. potassium). Hemolytic samples have a reddish color, and this color can interfere with the detection of other components.
In the case of icteric interference, the red/yellow color from bilirubin can also interfere with spectrophotometric measurements of other components.
Lipemic interference causes turbidity in the sample and can thereby affect turbidimetric detection methods.
Finally, the three interferences (H, I and L) can also react with the component you want to measure.

Statistics

Target values and accept intervals

Used accept intervals

Component	Accept interval, %	Reference
Bilirubin (conjugated)	20,5	Based on mean from three articles[1]
Cholesterol	8,6	EFLM Desirable
Creatinin	7,8	EFLM Desirable
Ferritin	21,9	EFLM Optimal
Lactatdehydrogenase	10,2	EFLM Minimum
Phosphate	9,6	EFLM Desirable
Potassium	7,4	EFLM Minimum
Hæmoglobin, H-indeks	12,2	Expert estimate
Bilirubin, I-indeks	29	Expert estimate
Lipid, L-indeks	22,5	Expert estimate

[1]Qi et al, Clin Chim Acta, 2016 Jan 15;452;87-91; Aarsand et al, Clin Chem. 2018 Sep;64(9):1380-1393; Ma et al, Clin Chem Lab Med. 2022;60(10):1648-1660.
[2]Expert estimate based on both EFLM requirements based on biological variation (tight) and expert estimate of outcome effect on components affected by the concentration of either H-, I- or L-index (broader). The chosen size of the acceptance limit seems to give an acceptable proportion of results that lie within/outside the limit assessed by historical data

For the examined index the target value for both Sample A and B is calculated as the average of all means for all manufacturers with more than three participants. It is called Special target value and marked with “S”.
For the two other indices the target value is calculated as the average of all means for all manufacturers with more than three participants for Sample A and marked with “S”. The target value for Sample B is the same as for Sample A and marked with “T” for Transferred target value from Sample A.
For the analyzed (non-index) components, the consensus mean of all participants´ results for Sample A is used as the target value. The target value is marked with an “M”. For Sample B the target value is the same as for Sample A and the target value is marked with “T”. For the component Phosphate, the target value is calculated as the mean of all participants´ results for Sample A measured up to and including Day 4 after the manufacturing date. The target value is marked with an “S”. For Sample B the target value is the same as for Sample A and marked with “T ”.

Units and intervals for H-, I- and L-index

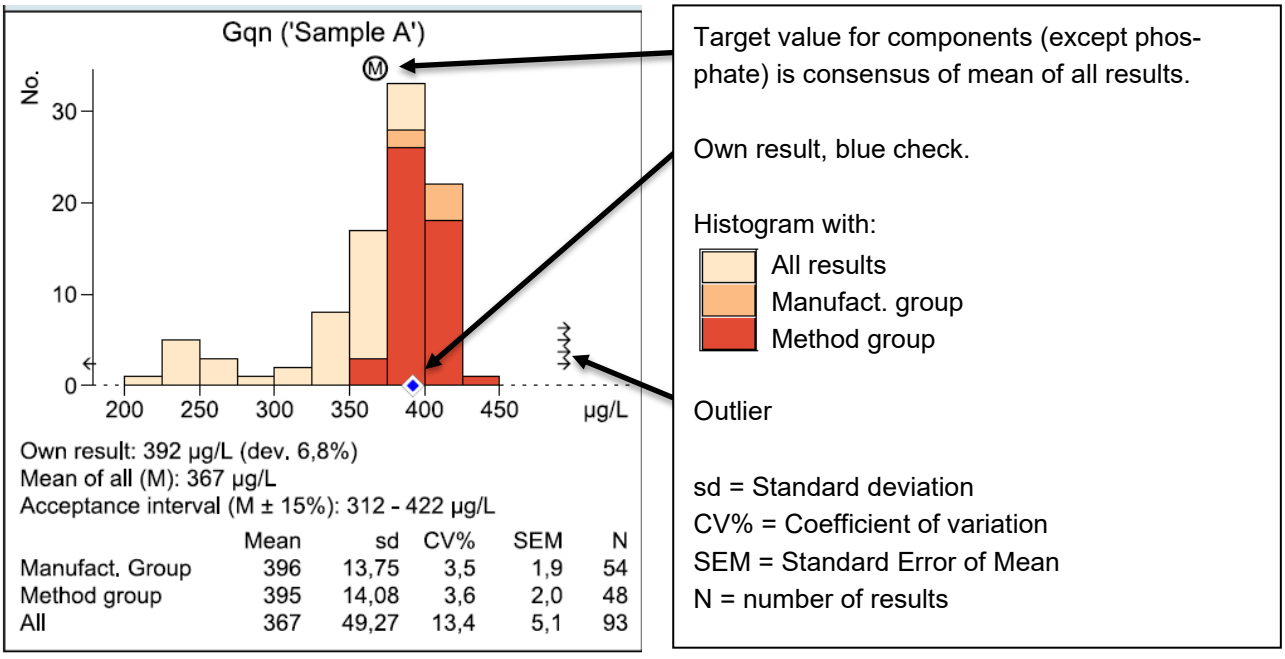
When results have been reported with a < or as an arbitrary index, the middle of the range is used as a quantitative result.
All results for the H, I and L indices are converted into the same unit for comparison.
”g/L” was chosen as a common unit for all results of the H index and L index, as it is easy to recognize results originally stated in mg/dL.
”µmol/L” was chosen as a common unit for all results of the icteric index.
Arbitrary units are converted into SI units according to information from the manufacturer.

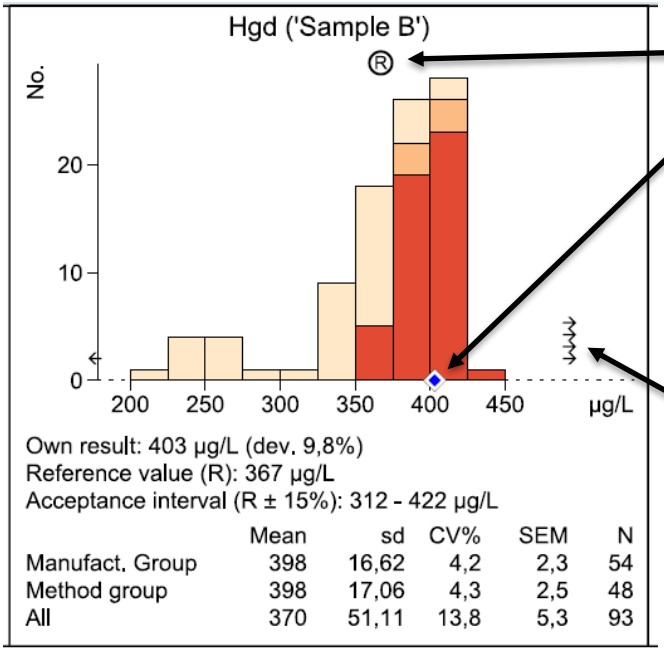
Guidance for interpretation of the graphic part

Component- and method heading

P- Ferritin{massek.} -	Instrument: Cobas
Producentgruppe: Roche	Metodegruppe: Cobas e-modul

Histogram





Target value for components in Sample B (except phosphate) is the same as Sample A.

Own result, blue check

Histogram with:
- All results
- Manufact. group
- Method group

Outlier

sd = Standard deviation
CV% = Coefficient of variation
SEM = Standard Error of Mean
N = number of results

For Sample A the target value for components except phosphate is marked with an (M). This is a mean of *all results*. For the H-, I- and L-index the target value is marked with (S) and is the mean of all means for all manufacturers with more than three participants. For phosphate the target value is marked with (S) and calculated from results up to and including Day 4.

For Sample B the target value for components except phosphate is the mean of Sample A and is marked with an (S). For the examined index the target value is marked with (S) and calculated as the average of all means for all manufacturers with more than three participants. For the two other indices and phosphate the target value is the same as for Sample A and marked with (T).

Overview of target values for indices and components:

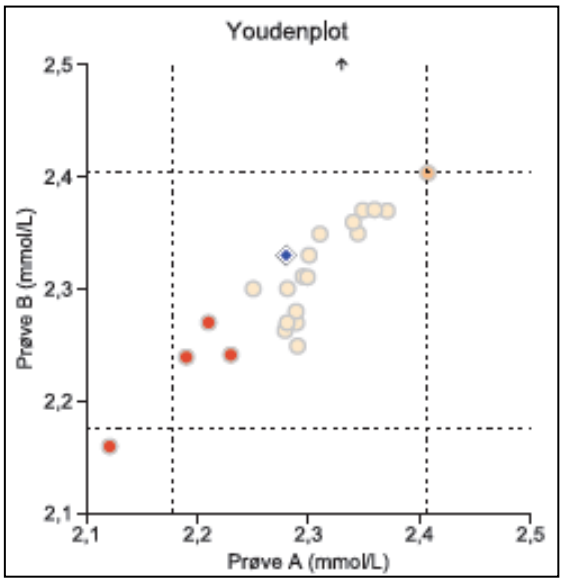
	Sample A	**Sample B**
Examined index	S – Special target value	S – Special target value
Two other indices	S – Special target value	T – Transferred target value from Sample A
Components except Phosphate	M – Mean of all	T – Transferred target value from Sample A
Phosphate	S – Special target value	T – Transferred target value from Sample A

Below the histogram the text is summed up and show the reported result and the deviation for the target value in %. In addition, you can see the accept interval and statistics for own instrument group with all the reported results. In the histogram, the following is also shown:

- sd is the standard deviation
- CV% is the variation coefficients, calculated as $^{sd}/_{mean} \cdot 100\%$.
- SEM is standard error of the mean value and is calculated as $^{sd}/_{\sqrt{number}}$.
- N is the number of results.

Outliers appears in the histogram and is shown by an arrow at the x-axis. Outliers in the HIL program are defined as ± 3,2 sd from target or set as manual outliers by DEKS if the sample is analyzed after “last day of analysis” or the result deviates to a (unrealistic) great extent.

Youden plot



The Youden plot shows the performance of the actual method for the two samples.