# HIL Test

cobas®

**HIL Test**

| REF | CONTENT | | SYSTEM |
|---|---|---|---|
| **07470045** 190 | 2300 | System-ID 07 2006 3 | **cobas t** 511<br>**cobas t** 711 |

**English**

**System information**

| Short name | ACN (application code number) |
|---|---|
| HIL Test | 28180 |

**Intended use**

In vitro test for the semi-quantitative determination of the lipemia index, hemolysis index and icterus index in citrated plasma on **cobas t** systems.

**Summary**

Medical laboratory tests can be affected by endogenous and exogenous constituents in the sample matrix. Some of these potentially interfering factors can be recognized in the pre-analytical phase by a coloured appearance of the sample, whereas others are detected only by means of additional information and/or by direct analysis. The limits at which the analysis can be made are described for each method subject to that interference. Nevertheless, interferences due to hemolysis (hemoglobin), icterus (bilirubin) and lipemia (turbidity) are difficult to predict because of their strong method-dependence.[1] An approximate quantification of these interferents is possible with the HIL Test which can be applied on the indicated Roche **cobas t** systems. The analyzers are capable of semi-quantitative measurement and reporting of the hemolysis index (H), icterus index (I) and lipemia index (L).

HIL Test results are an aid in the assessment of potential interferences due to hemolysis, icterus and lipemia.

**Hemolysis**

Hemolysis is defined as the release of intracellular components of erythrocytes and other blood cells into the extracellular space of blood. After the separation of blood cells, hemolysis is detected in plasma by its red colour caused by hemoglobin. It can appear in vivo (e.g. due to an extracorporeal circulation or during malaria parasite infection) as well as in vitro in all components of the pre-analytical phase (sampling, sample transport and storage). If in vitro hemolysis is present in a sample, it should be considered that a pre-activation of coagulation may have occurred.

**Icterus**

Icterus is defined as an elevated level of different bilirubin species (conjugated and unconjugated) in plasma. Increased levels of bilirubin can be caused by diseases or conditions which, through hemolytic processes, produce bilirubin faster than the liver can metabolize it. Liver immaturity and several other diseases in which the bilirubin conjugation mechanism is impaired cause similar elevations of circulating unconjugated bilirubin. Bile duct obstruction or damage to hepatocellular structure causes increases in the levels of both conjugated (direct) and unconjugated (indirect) bilirubin in the circulation.

**Lipemia**

Lipemia is defined as turbidity in plasma samples which is visible to the naked eye. The most frequent cause of lipemia is an elevated triglyceride concentration in plasma. This can be caused by food intake, a disturbance of lipoprotein metabolism or an infusion of lipids.

**IMPORTANT NOTE**

The HIL Test can not be used for the quantitative determination of hemoglobin, bilirubin or triglycerides.

**Test principle**

The HIL Test is based on calculations of absorbance measurements of the diluted samples at different wavelengths to provide a semi-quantitative measurement of hemolysis, icterus and lipemia levels present in citrated plasma samples.

The analyzer dilutes an aliquot of the patient specimen in saline solution (0.9 % sodium chloride) and measures the absorbance at 408, 588, 625 and 800 nm. From these absorbance values the instrument calculates HIL index values.

**Reagents - working solutions**

**cobas t** pack

**SR**[a)] Sodium chloride 9 %

a) Start reagent

SR is in position B and position C.

**Precautions and warnings**

For in vitro diagnostic use for health care professionals. Exercise the normal precautions required for handling all laboratory reagents.

Infectious or microbial waste:
Warning: handle waste as potentially biohazardous material. Dispose of waste according to accepted laboratory instructions and procedures.

Environmental hazards:
Apply all relevant local disposal regulations to determine the safe disposal.

Safety data sheet available for professional user on request.

This kit contains components classified as follows in accordance with the Regulation (EC) No. 1272/2008:

Product safety labeling follows EU GHS guidance.

Contact phone: all countries: +49-621-7590

Avoid foam formation in all reagents and sample types (specimens, calibrators and controls).

**Reagent handling**

The reagent in the cassette has been assembled into a ready-for-use unit (**cobas t** pack).

All information required for correct operation is available via the **cobas** link.

**Storage and stability**

Store at 2-8 °C.

Store the **cobas t** pack **upright**.

The unopened **cobas t** pack is stable up to the stated expiration date.

| Stability of the opened **cobas t** pack: | |
|---|---|
| on the **cobas t** analyzer | 12 weeks after piercing |

Do not freeze.

**Specimen collection and preparation**

Only the specimens listed below were tested and found acceptable:
3.2 % citrated human plasma

Use standard sampling tubes made of plastic or siliconized glass. Strictly observe the ratio of blood (9 parts) to sodium citrate solution 0.11 M (1 part).[2,3]

The sample types listed were tested with a selection of sample collection tubes that were commercially available at the time of testing, i.e. not all available tubes of all manufacturers were tested. Sample collection systems from various manufacturers may contain differing materials which could affect the test results in some cases. When processing samples in primary tubes (sample collection systems), follow the instructions of the tube manufacturer.

Centrifuge 15 minutes at 2500 g or such that the platelet count is < 10000 platelets/µL.

**Note:** Measure the HIL Test in parallel to the respective parameters.

**Materials provided**

See “Reagents – working solutions” section.

**Materials required (but not provided)**

- General laboratory equipment

**cobas t** coagulation analyzer. See User Assistance of the analyzer concerned for additionally required materials.

**Assay**

For optimum performance of the assay follow the directions given in this document. Refer to the appropriate User Assistance for analyzer-specific assay instructions.

The performance of applications not validated by Roche is not warranted and must be defined by the user.

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### Calibration

No calibration required.

### Calculation

**cobas t** systems automatically calculate the HIL index values of each sample.

The HIL index values have no unit.

### Limitations - interference

Measuring range, Limit of Blank, Limit of Detection and specific performance data as listed below refer to samples containing only one of the three interferents, either hemolysis, icterus or lipemia.

Samples containing more than one interferent might show deviations.

In particular, significant deviations from the true I index have been observed in artificial samples that were both, highly hemolytic and highly lipemic.

### Measuring range

For H-, I- and L-index: 5-100

### Limit of Blank and Limit of Detection

Limit of Blank H-, I- and L-index = 3

Limit of Detection H-, I- and L-index = 5

The Limit of Blank and Limit of Detection were determined in accordance with the CLSI (Clinical and Laboratory Standards Institute) EP17-A2 requirements. The Limit of Blank is the 95$^{th}$ percentile value from n = 60 measurements of analyte-free samples over several independent series. The Limit of Blank corresponds to the concentration below which analyte-free samples are found with a probability of 95 %.

The Limit of Detection is determined based on the Limit of Blank and the standard deviation of low concentration samples.

The Limit of Detection corresponds to the lowest analyte concentration which can be detected (value above the Limit of Blank with a probability of 95 %).

### Specific performance data

Representative performance data on the analyzers are given below. Results obtained in individual laboratories may differ.

### Precision

Precision was determined using human samples in an internal protocol with repeatability (n = 21). The following results were obtained:

### H index

| | Mean | SD | CV % |
|---|---|---|---|
| Sample 1 | 6.96 | 1.12 | 16.1 |
| Sample 2 | 9.68 | 0.745 | 7.7 |
| Sample 3 | 30.3 | 1.04 | 3.4 |
| Sample 4 | 51.4 | 1.13 | 2.2 |
| Sample 5 | 85.1 | 0.509 | 0.6 |

### I index[b)]

| | Mean | SD | CV % |
|---|---|---|---|
| Sample 1 | 5.99 | 0.422 | 7.0 |
| Sample 2 | 9.08 | 0.256 | 2.8 |
| Sample 3 | 27.9 | 0.443 | 1.6 |
| Sample 4 | 48.9 | 0.280 | 0.6 |
| Sample 5 | 87.0 | 0.591 | 0.7 |

b) Determined for samples containing conjugated bilirubin.

### I index[c)]

| | Mean | SD | CV % |
|---|---|---|---|
| Sample 1 | 6.42 | 0.353 | 5.5 |
| Sample 2 | 10.7 | 0.412 | 3.9 |
| Sample 3 | 32.5 | 0.521 | 1.6 |
| Sample 4 | 54.2 | 1.03 | 1.9 |
| Sample 5 | 86.2 | 0.624 | 0.7 |

c) Determined for samples containing unconjugated bilirubin.

### L index

| | Mean | SD | CV % |
|---|---|---|---|
| Sample 1 | 6.16 | 0.101 | 1.6 |
| Sample 2 | 11.4 | 0.154 | 1.4 |
| Sample 3 | 30.9 | 0.352 | 1.1 |
| Sample 4 | 51.3 | 0.621 | 1.2 |
| Sample 5 | 85.1 | 0.751 | 0.9 |

### References


1 Guder WG, da Fonseca-Wolheim F, Heil W, et al. The Haemolytic, Icteric and Lipemic Sample Recommendations Regarding their Recognition and Prevention of Clinically Relevant Interferences. J Lab Med 2000;24:357-364.

2 CLSI Document H21-A5, Vol.28, No.5, 2008. Collection, transport, and processing of blood specimens for testing plasma-based coagulation assays and molecular hemostasis assays; approved guideline, 5th edition.

3 CLSI Document H3-A6. Procedures for the collection of diagnostic blood specimens by venipuncture; approved standard - Sixth Edition, vol. 27, No. 26, 2007.


A point (period/stop) is always used in this Method Sheet as the decimal separator to mark the border between the integral and the fractional parts of a decimal numeral. Separators for thousands are not used.

For further information, please refer to the appropriate User Assistance for the relevant analyzer and Method Sheets of all necessary components.

Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established.

### Symbols

Roche Diagnostics uses the following symbols and signs in addition to those listed in the ISO 15223-1 standard (for USA: see dialog.roche.com for definition of symbols used):

| | |
|---|---|
| CONTENT | Contents of kit |
| SYSTEM | Analyzers/Instruments on which reagents can be used |
| REAGENT | Reagent |
| CALIBRATOR | Calibrator |
| → | Volume after reconstitution or mixing |
| GTIN | Global Trade Item Number |



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