

**Instructions For Use**

© 2020 Beckman Coulter, Inc. All rights reserved.



*For in vitro diagnostic use only.*

**ANNUAL REVIEW**

Reviewed by	Date	Reviewed by	Date

**PRINCIPLE****INTENDED USE**

Photometric test for the semi-quantitative assessment of lipaemia/turbidity, icterus and haemolysis (LIH) in human serum and plasma on Beckman Coulter AU analysers.

**SUMMARY AND EXPLANATION**

A number of diseases and pre-analytical conditions can result in increased concentrations of chromogens like bilirubin, haemoglobin and lipids/turbidity in body fluids. Chromogens can interfere with photometric tests.

The manufacturers of clinical reagents are responsible for the characterisation of the interference performance of the supplied test systems.

The users of these test systems should evaluate the sample quality and identify potentially interfering substances in these samples, and this evaluation is normally done by visual assessment. With the LIH reagent this assessment can be done on the AU Chemistry System.

**METHODOLOGY**

Patient samples are diluted with the LIH reagent and the absorbance is measured at 6 wavelengths. If one or more chromogen in a potentially interfering concentration is present in a sample, applicable flags will be generated and reported along with the results of the analyses performed on that sample. These flags characterise the kind of chromatic substance (LIP: Lipaemia/turbidity, ICT: Bilirubin and HEM: Haemoglobin) and the approximate concentration of the interferent (e.g.: +, ++, +++++, see following table).

<b>Approximate Concentration of Chromatic Substance</b>			
<b>Flag</b>	<b>LIP (mg/dL Intralipid)</b>	<b>ICT (mg/dL Bilirubin)</b>	<b>HEM (mg/dL Hemoglobin)</b>
N	< 40	< 2.5	< 50
+	40 – 99	2.5 – 4.9	50 – 99
++	100 – 199	5.0 – 9.9	100 – 199
+++	200 – 299	10 – 19.9	200 – 299
++++	300 – 500	20 – 40	300 – 500
+++++	> 500	> 40	> 500

If a particular sample is marked with one or more of the above flags, users should verify if the type or the level of the chromogen is a potential risk to the accuracy of the test results of that sample. This verification can be done with the aid of the reagent specific information from the 'INTERFERENCES' section of the relevant IFU.

## **SPECIMEN**

### **SPECIMEN COLLECTION AND PREPARATION**

Serum and Plasma. It is recommended that serum/plasma should be physically separated from contact with cells within two hours from the time of collection.

Use samples undiluted.

## **REAGENTS**

### **WARNING AND PRECAUTIONS**

Exercise the normal precautions required for handling all laboratory reagents.

Dispose of all waste material in accordance with local guidelines.

### **REACTIVE INGREDIENTS**

Sodium chloride      0.9%

Preservatives

The concentrations of the reactive components of the reagents shown on the kit label are the actual concentrations in the individual R1/R2 vials. The reagent composition which is shown in the Instructions For Use is the final concentration of these components in the reaction cuvette after addition of R1, Sample, and R2.

### **GHS HAZARD CLASSIFICATION**

LIH

WARNING



H317	May cause an allergic skin reaction.
H412	Harmful to aquatic life with long lasting effects.
P273	Avoid release to the environment.
P280	Wear protective gloves, protective clothing and eye/face protection.
P333+P313	If skin irritation or rash occurs: Get medical advice/attention.
P362+P364	Take off contaminated clothing and wash it before use.

reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1) < 0.05%

SDS

Safety Data Sheet is available at [techdocs.beckmancoulter.com](http://techdocs.beckmancoulter.com)

## REAGENT PREPARATION

The reagent is ready for use and can be placed directly on board the instrument.

## STORAGE AND STABILITY

The reagent is stable unopened up to the stated expiry date when stored at 2...25°C. Once open, reagent stored on board the instrument is stable for 90 days.

## CALIBRATION

### CALIBRATION INFORMATION

No calibration required.

## TESTING PROCEDURE(S)

Refer to the appropriate Beckman Coulter AU analyser User Guide/Instructions For Use (IFU) for analyser-specific assay instructions for the sample type as listed in the Intended Use statement.

## CALCULATIONS

The Beckman Coulter analysers automatically compute the LIH status of each sample.

## PROCEDURAL NOTES

### LIMITATIONS

The integrity of all indices should be visually verified if ABN flags are obtained.



## Icterus

Patient serum samples were used to compare the Icterus Index of this LIH reagent OSR62166 on the AU2700 against the Bilirubin reagent OSR6112 and against a visual assessment of the sample by three independent observers.

The results are summarized in the following tables.

Flag	Frequency of Icterus flags																								
+++++						4	<table border="1"> <tr> <td rowspan="2">ICT AU2700</td> <td>+ve</td> <td>7</td> <td>74</td> </tr> <tr> <td>-ve</td> <td>283</td> <td>5</td> </tr> <tr> <td colspan="2"></td> <td>-ve</td> <td>+ve</td> </tr> <tr> <td colspan="4" style="text-align: center;"><b>Visual Assessment</b></td> </tr> </table>				ICT AU2700	+ve	7	74	-ve	283	5			-ve	+ve	<b>Visual Assessment</b>			
ICT AU2700	+ve	7	74																						
	-ve	283	5																						
		-ve	+ve																						
<b>Visual Assessment</b>																									
++++					11	3																			
+++			2	15	1																				
++		1	20	10																					
+	5	12	4																						
N	449	1																							
	< 2.5	2.50-4.99	5.00-9.99	10.0-19.9	20.0-39.9	≥ 40																			
Bilirubin Concentration (mg/dL)																									

## Hemolysis

Patient serum samples were used to compare the Hemolysis Index of this LIH reagent OSR62166 on the AU2700 against the Total Hemoglobin reagent OSR6192 (without predilution) and against a visual assessment of the sample by three independent observers.

The results are summarized in the following tables.

Flag	Frequency of Hemolysis flags																								
+++++						0	<table border="1"> <tr> <td rowspan="2">HEM AU2700</td> <td>+ve</td> <td>1</td> <td>86</td> </tr> <tr> <td>-ve</td> <td>288</td> <td>4</td> </tr> <tr> <td colspan="2"></td> <td>-ve</td> <td>+ve</td> </tr> <tr> <td colspan="4" style="text-align: center;"><b>Visual Assessment</b></td> </tr> </table>				HEM AU2700	+ve	1	86	-ve	288	4			-ve	+ve	<b>Visual Assessment</b>			
HEM AU2700	+ve	1	86																						
	-ve	288	4																						
		-ve	+ve																						
<b>Visual Assessment</b>																									
++++					15																				
+++				10																					
++			24	3																					
+		30	8																						
N	359	26																							
	< 50	50 - 99	100-199	200-299	300-499	≥ 500																			
Hemoglobin Concentration (mg/dL)																									

Reference<sup>1,2,3,4,5,6</sup>

## ADDITIONAL INFORMATION

### REVISION HISTORY

Revised GHS section

### Preceding version revision history

IFU updated to add Vietnamese language.

## REFERENCES

1. Tietz NW. "Specimen Collection and Processing; Sources of Biological Variation," Textbook of Clinical Chemistry, 2<sup>nd</sup> Edition, W. B. Saunders, Philadelphia, PA (1994).
2. National Committee for Clinical Laboratory Standards, Procedures for the Handling and Processing of Blood Specimens, Approved Guideline, NCCLS publication H18-A, Villanova, PA (1990).
3. Tietz NW. "Clinical Guide to Laboratory Tests," 3rd Edition, W. B. Saunders, Philadelphia, PA (1995).
4. Henry JB ed. "Clinical Diagnosis and Management by Laboratory Methods," 18th Edition, W. B. Saunders, Philadelphia, PA (1991).
5. Friedman RB and Young DS. Effects of Disease on Clinical Laboratory Tests, 3rd Edition, AACC Press, Washington, D.C. (1997).
6. Young DS. Effects of Preanalytical Variables on Clinical Laboratory Tests, 2nd Edition, AACC Press, Washington, D.C. (1997).

**EC REP** Beckman Coulter Ireland Inc., Lismeehan, O'Callaghan's Mills Co. Clare, Ireland (001) 703-527-3887

 Beckman Coulter, Inc., 250 S. Kraemer Blvd., Brea, CA 92821 U.S.A.  
[www.beckmancoulter.com](http://www.beckmancoulter.com)