

# HUMAN ASSAYED MULTI-SERA - LEVEL 2 (HUM ASY CONTROL 2)

<b>CAT. NO.</b> HNI530	<b>GTIN:</b> 05055273203783	<b>SIZE:</b> 20 x 5ml
<b>CAT. NO.</b> HS2611	<b>GTIN:</b> 05055273203813	<b>SIZE:</b> 5 x 5ml
<b>LOT NO.</b> 1416UN	<b>EXPIRY:</b> 2023-06-28	

**INTENDED USE**

This product is intended for *in vitro* diagnostic use, in the quality control of diagnostic assays. The Human Assayed Multi-sera is for the control of accuracy.

**DEVICE DESCRIPTION**

The Human Assayed Multi-sera is supplied at 2 levels, level 2 and 3. Target values and ranges are supplied for the analytes listed in the values section at both levels.

**SAFETY PRECAUTIONS AND WARNINGS**

For *in vitro* diagnostic use only. Do not pipette by mouth. Exercise the normal precautions required for handling laboratory reagents.

Human source material, from which this product has been derived, has been tested at donor level for the Human Immunodeficiency Virus (HIV 1, HIV 2) antibody, Hepatitis B Surface Antigen (HbsAg), and Hepatitis C Virus (HCV) antibody and found to be NON-REACTIVE. FDA approved methods have been used to conduct these tests.

However, since no method can offer complete assurance as to the absence of infectious agents, this material and all patient samples should be handled as though capable of transmitting infectious diseases and disposed of accordingly.

Health and Safety Data Sheets are available on request.

**STORAGE AND STABILITY**

**OPENED:** Store refrigerated (+2°C to +8°C). Reconstituted serum is stable for 8 hours at +15°C to +25°C or 7 days at +2°C to +8°C, and 28 days when frozen once at -18°C to -24°C. (See Limitations)

**UNOPENED:** Store refrigerated (+2°C to +8°C). Stable to expiration date printed on individual vials.

**LIMITATIONS**

Alkaline Phosphatase levels in the reconstituted serum will rise over the stability period. It is recommended that the reconstituted serum is allowed to stand for 1 hour at +15°C to +25°C before measurement.

Bilirubin in the serum is light sensitive and it is recommended that the serum is stored in the dark. Stored in the dark, it is stable for 4 days at +2°C to +8°C. Do not store at +15°C to +25°C. Do not freeze.

Bacterial contamination of the reconstituted serum will cause reductions in the stability of many components.

Different lot numbers of this control should not be interchanged, as the values assigned to the controls vary from lot to lot.

The control should not be used as a calibration material.

**PREPARATION FOR USE**

The Human Assayed Multi-sera is supplied lyophilised.

- Carefully reconstitute each vial of lyophilised serum with exactly 5ml of distilled water at +15°C to +25°C. Close the bottle and allow to stand for 30 minutes before use. Ensure contents are completely dissolved by swirling gently. Avoid formation of foam. Do not shake.
- Refer to the Control section of the individual analyser application.
- Refrigerate any unused material. Prior to reuse, mix contents thoroughly.

**MATERIALS PROVIDED**

Human Assayed Multi-sera - Level 2 20 x 5ml / 5 x 5ml

**MATERIALS REQUIRED BUT NOT PROVIDED**

Volumetric pipette

**ASSIGNED VALUES**

Each batch of assayed human serum is submitted to reference laboratories for assignment.

## 人基质定值生化质控-血清-水平 2 (HUM ASY CONTROL 2)

货号. HNI530      **GTIN:** 05055273203783      规格: 20 x 5ml  
货号. HS2611      **GTIN:** 05055273203813      规格: 5 x 5ml  
批号. 1416UN      **效期:** 2023-06-28

### 预期用途

本产品适用于临床生化体外诊断的质量控制，作为定值质控监测靶值表中所列项目的准确性和重复性。

### 产品描述

人基质定值生化质控血清供应两种浓度，水平2和水平3，均提供各项的靶值和范围。

### 安全预防措施和警告

本产品仅用于体外诊断。禁止用口吸取。参照实验室对试剂的常规预防措施进行处理。  
本产品采用人源基质，对所有人源均进行了 HIV (HIV1、HIV2) 抗体、肝炎 B 表面抗原 (HbsAg) 和肝炎 C 病毒 (HCV) 抗体的测试，结果均呈阴性。检测这些项目所采用的方法均经 FDA 认证。

但是没有方法能够完全保证避免传染物质，因此该产品和所有的病人样品均应当按照能够传播疾病的样品小心处理。

本产品可提供 Health and Safety Data Sheets。

### 保存和稳定性

开瓶: 冷藏 2~8°C 保存。复溶后的血清在 15°C~25°C 稳定 8 小时，或可在 2~8°C 保存 7 天，或在 -18°C ~ -24°C 保存 28 天(见局限性)。

未开瓶: 冷藏 2~8 °C 可保存至效期末。

### 局限性

复溶后碱性磷酸酶水平在稳定期内会升高，推荐在复溶后 1 小时内检测。

胆红素为光敏项目，推荐避光保存，可在 2~8°C 保存 4 天，请勿在 15°C~25°C 保存，请勿冷冻保存。

复溶后的血清在受到细菌污染后，会导致多组分稳定性的下降。

不同批号产品赋值会有差别，请勿混合使用。

该产品不能用于校准。

### 预处理

人基质定值生化质控为冻干粉。

1. 小心往瓶中准确加入 5 ml 蒸馏水，在 15~25 °C 的条件下复溶，盖上瓶盖，使用前放置 30 分钟。轻轻翻转瓶子，确保内容物完全溶解；不要振荡，避免气泡的产生。

2. 参照分析仪的质控说明部分。

3. 未使用的产品请冷藏或冷冻，再次使用前，确保样品充分混合均匀。

### 产品提供

人基质定值生化质控-水平 2    20 x 5ml / 5 x 5ml

### 需要但未提供物质

量杯 移液管

### 赋值

各批次定值血清均送至参考实验室测试。

EC REP

Randox Teoranta, Meenmore,  
Dungloe, Donegal,  
F94 TV06, Ireland

(S): 27 Nov 20 pl

**HUMAN ASSAYED MULTI-SERA - LEVEL 2 (HUM ASY CONTROL 2)**

Cat. No. HN1530 / HS2611 Lot No. 1416UN Size: 20 x 5ml / 5 x 5ml Expiry: 2023-06-28					
Analyte	unit	Target	Range		methods
			low	high	
alpha-HBDH α-羟丁酸脱氢酶	U/l	221	188	254	BS-800,BS-820,BS-800M,BS-820M,BS-880,BS-890 37°C
	U/l	220	187	253	BS-2000,BS-2200,BS-2000M,BS-2200M 37°C
Albumin 白蛋白	g/l	40.2	34.1	46.3	BS-800,BS-820,BS-800M,BS-820M,BS-880,BS-890
	g/dl	4.02	3.41	4.63	
	g/l	40.2	34.1	46.3	BS-2000,BS-2200,BS-2000M,BS-2200M
	g/dl	4.02	3.41	4.63	
Alkaline Phosphatase 碱性磷酸酶	U/l	170	145	196	BS-800,BS-820,BS-800M,BS-820M,BS-880,BS-890 37°C
	U/l	174	148	200	BS-2000,BS-2200,BS-2000M,BS-2200M 37°C
ALT (GPT) 丙氨酸氨基转移酶	U/l	37.6	30.0	45.2	BS-800,BS-820,BS-800M,BS-820M,BS-880,BS-890 37°C
	U/l	38.3	30.6	46.0	BS-2000,BS-2200,BS-2000M,BS-2200M 37°C
Amylase Total 淀粉酶	U/l	91.9	78.1	106	BS-800,BS-820,BS-800M,BS-820M,BS-880,BS-890 37°C
	U/l	91.1	77.4	105	BS-2000,BS-2200,BS-2000M,BS-2200M 37°C
AST (GOT) 天门冬氨酸氨基转移酶	U/l	38.2	30.6	45.8	BS-800,BS-820,BS-800M,BS-820M,BS-880,BS-890 37°C
	U/l	37.8	30.3	45.3	BS-2000,BS-2200,BS-2000M,BS-2200M 37°C
Bile Acids 胆汁酸	μmol/l	22.7	18.2	27.2	BS-800,BS-820,BS-800M,BS-820M,BS-880,BS-890
	μmol/l	23.2	18.6	27.8	BS-2000,BS-2200,BS-2000M,BS-2200M
Bilirubin Direct - Diazo with Sulphanilic Acid 直接胆红素-对氨基苯磺酸重氮法	μmol/l	23.3	18.4	28.2	BS-800,BS-820,BS-800M,BS-820M,BS-880,BS-890
	mg/dl	1.36	1.08	1.65	
	μmol/l	23.5	18.6	28.4	BS-2000,BS-2200,BS-2000M,BS-2200M
	mg/dl	1.37	1.09	1.66	
Bilirubin Direct - Oxidation to Biliverdin/Vanadate 直接胆红素-胆绿素/钒酸盐氧化法	μmol/l	19.3	15.2	23.4	BS-800,BS-820,BS-800M,BS-820M,BS-880,BS-890
	mg/dl	1.13	0.890	1.37	
	μmol/l	19.2	15.1	23.3	BS-2000,BS-2200,BS-2000M,BS-2200M
	mg/dl	1.12	0.885	1.36	
Bilirubin Total - Diazo with Sulphanilic Acid 总胆红素-对氨基苯磺酸重氮法	μmol/l	30.3	23.9	36.7	BS-800,BS-820,BS-800M,BS-820M,BS-880,BS-890
	mg/dl	1.77	1.40	2.14	
	μmol/l	30.6	24.2	37.0	BS-2000,BS-2200,BS-2000M,BS-2200M
	mg/dl	1.79	1.41	2.16	
Bilirubin Total - Oxidation to Biliverdin/Vanadate 总胆红素-胆绿素/钒酸盐氧化法	μmol/l	27.8	22.0	33.6	BS-800,BS-820,BS-800M,BS-820M,BS-880,BS-890
	mg/dl	1.63	1.29	1.97	
	μmol/l	28.1	22.2	34.0	BS-2000,BS-2200,BS-2000M,BS-2200M
	mg/dl	1.64	1.30	1.99	
Calcium 钙	mmol/l	2.22	1.99	2.45	BS-800,BS-820,BS-800M,BS-820M,BS-880,BS-890
	mg/dl	8.90	7.99	9.82	
	mmol/l	2.24	2.01	2.47	BS-2000,BS-2200,BS-2000M,BS-2200M
	mg/dl	8.98	8.06	9.91	
Chloride 氯	mmol/l	97.9	90.2	106	BS-800,BS-820,BS-800M,BS-820M,BS-880,BS-890
	mmol/l	97.9	90.2	106	BS-2000,BS-2200,BS-2000M,BS-2200M
Cholesterol 胆固醇	mmol/l	4.09	3.56	4.62	BS-800,BS-820,BS-800M,BS-820M,BS-880,BS-890
	mg/dl	158	138	179	
	mmol/l	4.08	3.55	4.61	BS-2000,BS-2200,BS-2000M,BS-2200M
	mg/dl	158	137	178	
Cholinesterase 胆碱酯酶	U/l	5400	4320	6480	BS-800,BS-820,BS-800M,BS-820M,BS-880,BS-890 37°C
	U/l	5383	4306	6460	BS-2000,BS-2200,BS-2000M,BS-2200M 37°C
CK Total 肌酸激酶 (总)	U/l	170	140	201	BS-800,BS-820,BS-800M,BS-820M,BS-880,BS-890 37°C
	U/l	171	141	202	BS-2000,BS-2200,BS-2000M,BS-2200M 37°C
Creatinine 肌酐	μmol/l	144	116	173	BS-800,BS-820,BS-800M,BS-820M,BS-880,BS-890
	mg/dl	1.63	1.31	1.96	
	μmol/l	146	117	175	BS-2000,BS-2200,BS-2000M,BS-2200M
	mg/dl	1.65	1.32	1.98	
D-3-Hydroxybutyrate D-3-羟基丁酸	mmol/l	0.289	0.245	0.333	BS-800,BS-820,BS-800M,BS-820M,BS-880,BS-890
	mmol/l	0.290	0.246	0.334	BS-2000,BS-2200,BS-2000M,BS-2200M
gamma-GT γ-谷氨酰氨基转移酶	U/l	51.7	44.0	59.4	BS-800,BS-820,BS-800M,BS-820M,BS-880,BS-890 37°C
	U/l	51.0	43.4	58.6	BS-2000,BS-2200,BS-2000M,BS-2200M 37°C
Glucose oxidase 葡萄糖-葡萄糖氧化酶法	mmol/l	5.90	5.01	6.79	BS-800,BS-820,BS-800M,BS-820M,BS-880,BS-890
	mg/dl	106	90.3	122	
	mmol/l	6.00	5.09	6.91	BS-2000,BS-2200,BS-2000M,BS-2200M
	mg/dl	108	91.8	124	
Glucose - Hexokinase 葡萄糖-己糖激酶法	mmol/l	5.90	5.01	6.79	BS-800,BS-820,BS-800M,BS-820M,BS-880,BS-890
	mg/dl	106	90.2	122	
	mmol/l	6.00	5.09	6.91	BS-2000,BS-2200,BS-2000M,BS-2200M
	mg/dl	108	91.8	124	

**HUMAN ASSAYED MULTI-SERA - LEVEL 2 (HUM ASY CONTROL 2)**

Cat. No. HN1530 / HS2611 Lot No. 1416UN Size: 20 x 5ml / 5 x 5ml Expiry: 2023-06-28					
Analyte	unit	Target	Range		methods
			low	high	
HDL - Cholesterol HDL 胆固醇	mmol/l	1.39	1.18	1.60	BS-800,BS-820,BS-800M,BS-820M,BS-880,BS-890
	mg/dl	53.7	45.6	61.8	
	mmol/l	1.37	1.16	1.58	BS-2000,BS-2200,BS-2000M,BS-2200M
Iron 铁	mg/dl	53.0	45.0	61.0	BS-800,BS-820,BS-800M,BS-820M,BS-880,BS-890
	μmol/l	18.7	15.4	22.0	
	μg/dl	104	85.8	123	BS-2000,BS-2200,BS-2000M,BS-2200M
LD (LDH) 乳酸脱氢酶	U/l	18.8	15.4	22.2	BS-800,BS-820,BS-800M,BS-820M,BS-880,BS-890 37°C
	U/l	216	184	249	
	U/l	214	182	247	BS-2000,BS-2200,BS-2000M,BS-2200M 37°C
Lipase 脂肪酶	U/l	28.5	22.8	34.2	BS-800,BS-820,BS-800M,BS-820M,BS-880,BS-890 37°C
	U/l	28.2	22.5	33.9	
Magnesium 镁	mmol/l	0.874	0.770	0.978	BS-800,BS-820,BS-800M,BS-820M,BS-880,BS-890
	mg/dl	2.12	1.87	2.38	
	mmol/l	0.890	0.784	0.996	BS-2000,BS-2200,BS-2000M,BS-2200M
	mg/dl	2.16	1.91	2.42	
Phosphate Inorganic 无机磷	mmol/l	1.36	1.15	1.57	BS-800,BS-820,BS-800M,BS-820M,BS-880,BS-890
	mg/dl	4.22	3.57	4.86	
	mmol/l	1.37	1.16	1.58	BS-2000,BS-2200,BS-2000M,BS-2200M
	mg/dl	4.25	3.60	4.89	
Potassium 钾	mmol/l	4.03	3.71	4.35	BS-800,BS-820,BS-800M,BS-820M,BS-880,BS-890
	mmol/l	4.03	3.71	4.35	
Protein Total 总蛋白	g/l	60.1	48.1	72.1	BS-800,BS-820,BS-800M,BS-820M,BS-880,BS-890
	g/dl	6.01	4.81	7.21	
	g/l	60.1	48.1	72.1	BS-2000,BS-2200,BS-2000M,BS-2200M
	g/dl	6.01	4.81	7.21	
Sodium 钠	mmol/l	143	136	150	BS-800,BS-820,BS-800M,BS-820M,BS-880,BS-890
	mmol/l	143	136	150	
Triglycerides 甘油三酸酯	mmol/l	1.06	0.889	1.23	BS-800,BS-820,BS-800M,BS-820M,BS-880,BS-890
	mg/dl	93.8	78.7	109	
	mmol/l	1.04	0.872	1.21	BS-2000,BS-2200,BS-2000M,BS-2200M
	mg/dl	92.0	77.2	107	
Urea 尿素	mmol/l	7.20	6.11	8.29	BS-800,BS-820,BS-800M,BS-820M,BS-880,BS-890
	mg/dl	43.2	36.7	49.8	
	mmol/l	7.20	6.11	8.29	BS-2000,BS-2200,BS-2000M,BS-2200M
	mg/dl	43.2	36.7	49.8	
Uric Acid (Urate) 尿酸	mmol/l	0.338	0.293	0.383	BS-800,BS-820,BS-800M,BS-820M,BS-880,BS-890
	mg/dl	5.68	4.93	6.43	
	mmol/l	0.338	0.294	0.383	BS-2000,BS-2200,BS-2000M,BS-2200M
	mg/dl	5.69	4.94	6.44	