

## Hematology Analyzer Reagent

Code	Name	Mode	Packing	Applied
<b>URIT</b>				
	<b>Diluent</b>	<b>URIT D 31</b>	<b>20L</b>	<b>URIT 3-Part Hematology Analyzer</b>
U7023134M	Diluent	URIT D 31	5L	
<b>U7034135M</b>	<b>Detergent</b>	<b>URIT D 41</b>	<b>20L</b>	
U7034134M	Detergent	URIT D 41	5L	
<b>U7012112M</b>	<b>Lytic Reagent</b>	<b>URIT L 21</b>	<b>500ml</b>	
U7012113M	Lytic Reagent	URIT L 21	1L	
<b>U7034151M</b>	<b>Probe Cleaner</b>	<b>URIT D 43</b>	<b>100ml</b>	
<b>URIT</b>				
Code	Name	Mode	Packing	Applied
U7023136M	Diluent	URIT 5D 11	20L	<b>URIT 5-Diff Hematology Analyzer</b>
U7023136P	Diluent	URIT 5D 11	5L	
U7023136M	Detergent	URIT D 46	20L	
U7023136P	Detergent	URIT D 46	5L	
U7012125N	Lytic Reagent	URIT 5L 11	1L	
U7012125M	Lytic Reagent	URIT 5L 11	500ml	
U7034140M	Sheath	URIT 5S 11	20L	
U7034140N	Sheath	URIT 5S 11	10L	
U7034151M	Probe Cleaner	URIT D 43	100ml	
	Close reagent card			
	RET Reagent		4ml/unit	
U7100210B	RET Reagent		4ml×100units	
U7100210C	RET Reagent		4ml×50units	

## Reagents for URIT-3020 Plus

### Lytic Reagent

Model: URIT L21

Specification: 500 mL/1 L



500 mL



1 L

### Diluent

Model: URIT D31

Specification: 5/10/20 L



5 L



10 L



20 L

### Detergent

Model: URIT D41

Specification: 5/10/20 L



5 L



10 L



20 L

## Control Material for URIT Hematology Analyzer

Model: URIT QC11

Specification: 3 mL\*6



## Calibration for URIT Hematology Analyzer

Model: URIT CA11

Specification: 3 mL\*6



## URIT Medical Electronic Co., Ltd.

Head Office

Add.: No. D-07 Information Industry District, High-tech Zone, Guilin, Guangxi 541004, P. R. China

Tel: +86-773-2288586 Fax: +86-773-2288560

E-mail: export@uritest.com service@uritest.com

# Operation Instruction for Probe Cleaner

**【Name】** Probe Cleaner

**【Model】** URIT D43

**【Specification】** Refer to the label.

**【Applicability】**

Probe Cleaner is appropriate to series URIT automated hematology analyzers.

**【Intended Use】**

Probe Cleaner is a reagent used to clean the instrument's probe or pipe. And it also can be used for daily maintenance.

**【Ingredient】** Sodium hypochlorite: 2%.

**【Restrictions, Precautions and Notices】**

1. Use the Probe Cleaner under the professional technician's guidance.
2. Avoid contact with skin and eyes. In case of contact, rinse immediately with plenty of water or seek medical advice.
3. Avoid inhaling the evaporated Probe Cleaner.
4. Tight up the container's cap to prevent from volatilization and contamination.
5. Dispose the remains after 60 days of use after unscrewing the Probe Cleaner container.

**【Storage and shelf life】**

1. Store in a dark place, keep away from direct sunlight, temperature should be 2°C-40°C.
2. Valid for 12 months, the reagent is considered invalid after unsealing for 60 days.

**【Operations】**

Click Clean in operation interface, put the 2ml probe cleaner under the probe and then click OK to start to clean. See the Operation Manual for details.

**【Sample Requirement】**

Not applicable.

**【Microbiological State】**

Not applicable.

**【Performance Parameter】**

1. pH value=  $13.00 \pm 1.00$ ,  $(25 \pm 1) ^\circ\text{C}$
2. Blank value:  $\text{WBC} \leq 0.5 \times 10^9 / \text{L}$ ,  $\text{RBC} \leq 0.1 \times 10^{12} / \text{L}$ ,  $\text{HGB} \leq 5\text{g} / \text{L}$ ,  $\text{PLT} \leq 20 \times 10^9 / \text{L}$ .
3. Difference between batches:  $\Delta\text{pH value} \leq 2.0$ .

**【Calculation and interpretation of analytical results】**

Not applicable.

**【Changes on Processes and Performance】**

Not applicable.

**【Traceability】**

Not applicable.

**【Reference Range】**

Not applicable.

**【Limitations】**

Not applicable.

**【Principle】**

Not applicable.

**【Reference】**

Not applicable.

**【Production Date】** Refer to the packing box or label.

**【Service Life】** Refer to the packing box or label.

**【Symbols on Vial Label and Packing Box】**



Use-by date



Batch code



Keep away from sunlight



Temperature limit



Date of manufacture



Manufacturer



Consult instructions for use



In Vitro Diagnostic medical device



Authorized representative in the European Community



**URIT Medical Electronic Co.,Ltd.**

No. D-07 Information Industry District, High-Tech Zone, Guilin, Guangxi 541004, P.R. China.

Tel: +86 (773) 2288586

Fax: +86 (773) 2288560

Email: [service@uritest.com](mailto:service@uritest.com)

<http://www.urit.com>

Manufacturer: **URIT Medical Electronic Co., Ltd**



Wellkang Ltd

Enterprise Hub, NW Business Complex,

1 Beraghmore Rd. Derry, BT48 8SE,

N. Ireland,UK

**【Release date】** In June 2020

**【Version】** 06/2020

# Operation Instruction for Diluent

**【Name】** Diluent

**【Model】** URIT D 31

**【Microbiological State】** Not applicable.

**【Intended Use】**

Diluent is appropriate to series of URIT automated hematology analyzers. With the function of measuring the blood cell content, it has an important effect to clinical diagnosis.

**【Restrictions, Precautions and Notices】**

1. Use the diluent under the professional technician's guidance.
2. This product should not be consumed, if so, please see a doctor immediately.
3. Avoid contact with skin and eyes. In case of contact, rinse immediately with plenty of water or seek medical advice.
4. Deal with the waste according to the local regulations.

**【Ingredients】** Sodium chloride, anhydrous sodium sulfate, preservative solution and the buffer solution.

**【Storage and Shelf Life】**

This product will be stable for 24 months when stored unopened at 2°C~40°C and away from sunlight. Once opened, this product should be consumed within 60 days and stored at 15°C~30°C.

**【Applicability】** It's used on URIT Automated Hematology Analyzer.

**【Blood Samples】**

1. The blood samples should be venous and capillary specimens collected in EDTA-K2 anticoagulant. Coagulated, hemolysis and lipoidaemia samples cannot be measured.
2. Blood samples should be stored at 2°C~8°C.

**【Operations】**

1. Inject the diluent inlet tubing into the lyse container, exhaust air in the container and tighten the lid. Click Change in maintenance interface. Do the blank count in counting interface and make sure that the blank value meets the standards.
2. Place the diluent beneath the analyzer.
3. Avoid direct sunlight, keep away from cooling or heating air outlet, use it at 15°C~30°C.

**【Performance】**

1. pH value:  $7.45 \pm 0.20$  at  $(25 \pm 1) ^\circ\text{C}$ .
2.  $\rho = (18.50 \pm 0.50) \text{ mS / cm}$  at  $(25 \pm 1) ^\circ\text{C}$ .
3. Osmotic concentration =  $(320 \pm 10) \text{ mOsm / kg}$ .
4. Particle counting: if the particle size is  $\geq 2.5 \text{ fL}$ , particle counting should be  $\leq 2.5 \times 10^5/\text{L}$ .
5. Accuracy: WBC count is within  $\pm 7.5\%$ , RBC count is within  $\pm 3.0\%$ , HGB count is within  $\pm 3.5\%$ , PLT count is within  $\pm 10\%$ , MCV count is within  $\pm 3.0\%$ .
6. Batch differences:  $\Delta\text{PH value} \leq 0.20$ , Conductivity  $\leq 0.50 \text{ mS / cm}$ , osmotic concentration  $\leq 10 \text{ mOsm / kg}$ .

**【Test Results】**

1. Test results please take reference of the normal range values.
2. If the test result is out of the range of reference value, flagged results will be marked with letter "L" or "H". "L" means the result is below the lower limit; "H" means the result is higher than the upper limit.

**【Changes on Processes and Performance】**

1. Tight up the container's cap to prevent from volatilization and contamination. Dispose the remains after 60 days of use after unscrewing the container.
2. If product has been frozen, let product warm to room temperature, and then gently invert product to mix it completely. Verify background results before use.
3. Please note that the reagent shall match with analyzer model. Please do not use the reagent produced by other company, otherwise it may cause measurement errors.

**【Quality Control】**

Detect three pieces of products in each production lot, two of them should be the first box and the last box in manufacturing process. The production lot shall be determined to be unqualified if there one does not meet inspection standards.

**【Quality Control and Traceability of Calibrators】**

Not applicable.

**【Reference Range】**

Items	Adult male	Adult female	Children	Newborn
WBC ( $\times 10^9/L$ )	3.5 ~ 9.5	3.5 ~ 9.5	5.0 ~ 12.0	15.0 ~ 20.0
LY/LYM ( % )	20.0 ~ 50.0	20.0 ~ 50.0	20.0 ~ 40.0	20.0 ~ 40.0
MO/MID ( % )	3.0 ~ 10.0	3.0 ~ 10.0	1.0 ~ 15.0	1.0 ~ 15.0
GR/GRAN ( % )	40.0 ~ 75.0	40.0 ~ 75.0	50.0 ~ 70.0	50.0 ~ 70.0
LY/LYM ( $\times 10^9/L$ )	1.1 ~ 3.2	1.1 ~ 3.2	1.0 ~ 4.1	1.0 ~ 4.1
MO/MID ( $\times 10^9/L$ )	0.1 ~ 0.6	0.1 ~ 0.6	0.1 ~ 1.8	0.1 ~ 1.8
GR/GRAN ( $\times 10^9/L$ )	1.8 ~ 6.3	1.8 ~ 6.3	2.0 ~ 7.8	2.0 ~ 7.8
RBC ( $\times 10^{12}/L$ )	4.30 ~ 5.80	3.80 ~ 5.10	4.00 ~ 6.00	6.00 ~ 7.00
HGB ( g/L )	130 ~ 175	115 ~ 150	110 ~ 150	170 ~ 200
HCT ( L/L )	0.40 ~ 0.50	0.35 ~ 0.45	0.36 ~ 0.48	0.36 ~ 0.48
MCV ( fL )	82.0 ~ 100.0	82.0 ~ 100.0	73.0 ~ 87.0	70.0 ~ 87.0
MCH ( pg )	27.0 ~ 34.0	27.0 ~ 34.0	26.0 ~ 32.0	26.0 ~ 32.0
MCHC ( g/L )	316 ~ 354	316 ~ 354	320 ~ 360	320 ~ 360
RDW-CV ( % )	11.5 ~ 14.5	11.5 ~ 14.5	11.5 ~ 14.5	11.5 ~ 14.5
RDW-SD ( fL )	37.0 ~ 54.0	37.0 ~ 54.0	37.0 ~ 54.0	37.0 ~ 54.0
PLT ( $\times 10^9/L$ )	125 ~ 350	125 ~ 350	100 ~ 300	100 ~ 300
PDW ( % )	10.0 ~ 14.0	10.0 ~ 14.0	10.0 ~ 14.0	10.0 ~ 14.0
MPV ( fL )	7.4 ~ 10.4	7.4 ~ 10.4	7.4 ~ 10.4	7.4 ~ 10.4
PCT ( fL )	0.10 ~ 0.28	0.10 ~ 0.28	0.10 ~ 0.28	0.10 ~ 0.28


**【Reference】**

- 1.Cong Yulong, Editor. Clinical laboratory equipment, the third volume, Reagents and consumables, wy, Beijing, Science Press,2016.4.
- 2.Zhao Guizhi, Clinical Laboratory Science. Chengdu: Sichuan Science and Technology Press, 1999.05.

**【Production Date】** Refer to the packing box or label.


**【Service Life】** Refer to the packing box or label.

**【Symbols on Packing Box and Label】**

-  Use by
-  **LOT** Batch code
-  Keep away from sunlight
-  Temperature limitation
-  Date of manufacture
-  Manufacturer
-  Consult instructions for use

**IVD** In Vitro Diagnostic medical device

**EC REP** Authorized representative in the European Community

 **URIT Medical Electronic Co., Ltd.**

No. D-07 Information Industry District, High-Tech Zone, Guilin, Guangxi 541004, P.R.China.

Tel: +86 ( 773 ) 2288586 Fax: +86 ( 773 ) 2288560

Web: www.urit.com Email: service@uritest.com

Supplied by: **URIT Medical Electronic Co., Ltd.**



Wellkang Ltd  
Enterprise Hub, NW Business Complex,  
1 Beraghmore Rd. Derry, BT48 8SE, N. Ireland,UK



**【Release date】** In October 2020

**【Version】** 05/2019-C1

# Operation Instruction for Lytic Reagent

**【Name】** Lytic Reagent

**【Model】** URIT L 21

**【Specifications】** Refer to the packing box or label.

**【Microbiological State】**

Not applicable.

**【Intended Use】**

Lyse is appropriate to series of URIT automated hematology analyzers. With the function of measuring the blood cell content, it has an important effect to clinical diagnosis.

**【Restrictions, Precautions and Notices】**

1. Use the Lyse under the professional technician's guidance.
2. This product should not be consumed, if so, please see a doctor immediately.
3. Avoid contact with skin and eyes. In case of contact, rinse immediately with plenty of water or seek medical advice.
4. Deal with the waste according to the local regulations.

**【Ingredient】**

Boric acid, borax, sodium dodecyl trimethyl ammonium chloride, cetyl trimethyl ammonium bromide accompanied by water.

**【Storage and Stability】**

1. Store in a dark place, keep away from direct sunlight, temperature should be 2°C-40°C.
2. Valid for 24 months, the reagent is considered invalid after unsealing for 60 days.

**【Applicability】** It's used on URIT Automated Hematology Analyzer.

**【Blood Samples】**

1. The blood samples should be venous and capillary specimens collected in EDTA-K<sub>2</sub> anticoagulant. Coagulated, hemolysis and lipidaemia samples cannot be measured.
2. Blood samples should be stored at 2°C~8°C.

**【Operations】**

1. When testing by quasi-automated hematology analyzer, the diluter samples the anticoagulated blood automatically and discharges a mixture of blood and diluents for WBC and HGB testing. Mix the mixture and diluents which is used for RBC and PLT testing. Add the lyse to the cup of WBC probe filled with mixture, it is used to classify the WBC, HGB and WBC.
2. When testing by automated hematology analyzer, the analyzer adds blood and relative reagents automatically.

**【Performance】**

1. pH value:  $7.60 \pm 0.20$  at  $(25 \pm 1) ^\circ\text{C}$ .
2. Blank value:  $\text{WBC} \leq 0.2 \times 10^9 / \text{L}$ ,  $\text{HGB} \leq 1\text{g} / \text{L}$ .

**【Test Results】**

1. Test results please take reference of the normal range values.
2. If the test result is out of the range of reference value, flagged results will be marked with letter "L" or "H". "L" means the result is below the lower limit; "H" means the result is higher than the upper limit.

**【Changes on Processes and Performance】**

1. Tight up the container's cap to prevent from volatilization and contamination.
2. Dispose the remains after 60 days of use after unscrewing the container.

**【Quality Control】**

Detect three pieces of products in each production lot, two of them should be the first box and the last box in

manufacturing process. The production lot shall be determined to be unqualified if there one does not meet inspection standards.

**【Quality Control and Traceability of Calibrators】** Not applicable.

**【Reference Range】**

Items	Adult male	Adult female	Children	Newborn
WBC ( $\times 10^9/L$ )	3.5~9.5	3.5~9.5	5.0~12.0	15.0~20.0
LY/LYM (%)	20.0~50.0	20.0~50.0	20.0~40.0	20.0~40.0
MO/MID (%)	3.0~10.0	3.0~10.0	1.0~15.0	1.0~15.0
GR/GRAN (%)	40.0~75.0	40.0~75.0	50.0~70.0	50.0~70.0
LY/LYM ( $\times 10^9/L$ )	1.1~3.2	1.1~3.2	1.0~4.1	1.0~4.1
MO/MID ( $\times 10^9/L$ )	0.1~0.6	0.1~0.6	0.1~1.8	0.1~1.8
GR/GRAN ( $\times 10^9/L$ )	1.8~6.3	1.8~6.3	2.0~7.8	2.0~7.8
RBC ( $\times 10^{12}/L$ )	4.30~5.80	3.80~5.10	4.00~6.00	6.00~7.00
HGB (g/L)	130~175	115~150	110~150	170~200
HCT (L/L)	0.40~0.50	0.35~0.45	0.36~0.48	0.36~0.48
MCV (fL)	82.0~100.0	82.0~100.0	73.0~87.0	70.0~87.0
MCH (pg)	27.0~34.0	27.0~34.0	26.0~32.0	26.0~32.0
MCHC (g/L)	316~354	316~354	320~360	320~360
RDW-CV (%)	11.5~14.5	11.5~14.5	11.5~14.5	11.5~14.5
RDW-SD (fL)	37.0~54.0	37.0~54.0	37.0~54.0	37.0~54.0
PLT ( $\times 10^9/L$ )	125~350	125~350	100~300	100~300
PDW (%)	10.0~14.0	10.0~14.0	10.0~14.0	10.0~14.0
MPV (fL)	7.4~10.4	7.4~10.4	7.4~10.4	7.4~10.4
PCT (fL)	0.10~0.28	0.10~0.28	0.10~0.28	0.10~0.28

**【Reference】**

1. Cong Yulong, Editor. Clinical laboratory equipment, the third volume, Reagents and consumables, wy, Beijing, Science Press, 2016.4.
2. Zhao Guizhi, Clinical Laboratory Science. Chengdu: Sichuan Science and Technology Press, 1999.05.
3. WS/T 405-2012. Blood cell analysis reference interval.

**【Production Date】** Refer to the packing box or label.

**【Service Life】** Refer to the packing box or label.

**【Symbols on Packing Box and Label】**

 Use by  Batch code  Keep away from sunlight  Temperature limitation

 Date of manufacture  Manufacturer  Consult instructions for use

 In Vitro Diagnostic medical device

 Authorized representative in the European Community

 **URIT Medical Electronic Co., Ltd.**

No. D-07 Information Industry District, High-Tech Zone, Guilin, Guangxi 541004, P.R.China.

Tel: +86 (773) 2288586 Fax: +86 (773) 2288560

Web: www.urit.com Email: service@uritest.com

Supplied by: **URIT Medical Electronic Co., Ltd.**



Wellkang Ltd  
Enterprise Hub, NW Business Complex,  
1 Beraghmore Rd. Derry, BT48 8SE, N. Ireland, UK



**【Release date】** In Oct 2020

**【Version】** 05/2019-C1



# Operation Instruction for Detergent

**【Name】** Detergent

**【Model】** URIT D 41

**【Microbiological State】** Not applicable

**【Intended Use】**

With the function of cleaning, it has an important effect to clinical diagnosis.

**【Restrictions, Precautions and Notices】**

1. Use the detergent under the professional technician's guidance.
2. This product should not be consumed, if so, please see a doctor immediately.
3. Avoid contact with skin and eyes. In case of contact, rinse immediately with plenty of water or seek medical advice.
4. Deal with the waste according to the local regulations.

**【Ingredients】**

Sodium chloride, anhydrous sodium sulfate, the buffer solution and surfactant

**【Storage and Shelf Life】**

This product will be stable for 24 months when stored unopened at 2°C~40°C and away from sunlight. Once opened, this product should be consumed within 60 days and stored at 15°C~ 30°C.

**【Applicability】** It's used on URIT Automated Hematology Analyzer.

**【Blood Samples】**

1. The blood samples should be venous and capillary specimens collected in EDTA-K<sub>2</sub> anticoagulant. Coagulated, hemolysis and lipoidaemia samples cannot be measured.
2. Blood samples should be stored at 2°C~8°C.

**【Operations】**

1. Inject the detergent inlet tubing into the detergent container, exhaust air in the container and tighten the lid. Click Change in maintenance interface. Do the blank count in counting interface and make sure that the blank value meets the standards.
2. Place the reagent beneath the analyzer.
3. Avoid direct sunlight, keep away from cooling or heating air outlet, use it at 15°C~30°C.

**【Performance】**

1. pH value: 7.40 ± 0.30 at (25 ± 1) °C.
2. Blank value: WBC ≤ 0.3 × 10<sup>9</sup> / L, RBC ≤ 0.05 × 10<sup>12</sup> / L, PLT ≤ 10 × 10<sup>9</sup> / L, HGB ≤ 2g / L.
3. Batch differences: ΔPH value ≤ 0.60.

**【Test Results】**

1. Test results please take reference of the normal range values.
2. If the test result is out of the range of reference value, flagged results will be marked with letter "L" or "H". "L" means the result is below the lower limit; "H" means the result is higher than the upper limit.

**【Changes on Processes and Performance】**

1. Tight up the container's cap to prevent from volatilization and contamination. Dispose the remains after 60 days of use after unscrewing the container.
2. If product has been frozen, let product warm to room temperature, and then gently

mix it. Verify background results before use.

3. Please note that the reagent shall match with analyzer model. Please do not use the reagent produced by other company, otherwise it may cause measurement errors.

**【Quality Control】**

Detect three pieces of products in each production lot, two of them should be the first box and the last box in manufacturing process. The production lot shall be determined to be unqualified if there one does not meet inspection standards.

**【Quality Control and Traceability of Calibrators】**

Not applicable

**【Reference Range】**

Not applicable

**【Reference】**

1. Cong Yulong, Editor . Clinical laboratory equipment , the third volume, Reagents and consumables, wy, Beijing, Science Press, 2016.4.

2. Zhao Guizhi, Clinical Laboratory Science. Chengdu: Sichuan Science and Technology Press, 1999.05.

**【Production Date】** Refer to the packing box or label.


**【Service Life】** Refer to the packing box or label.


**【Symbols on Packing Box and Label】**

 Use by       Batch code       Keep away from sunlight

 Temperature limitation       Date of manufacture       Manufacturer      Consult

 instructions for use       In Vitro Diagnostic medical device

 Authorized representative in the European Community

 URIT Medical Electronic Co., Ltd.  
No. D-07 Information Industry District, High-Tech Zone, Guilin, Guangxi 541004, P.R.China.

Tel: +86(773)2288586

Fax: +86(773)2288560

Web: www.urit.com

Email: service@uritest.com

Supplied by : URIT Medical Electronic Co., Ltd.



Wellkang Ltd

Enterprise Hub, NW Business Complex,  
1 Beraghmore Rd. Derry, BT48 8SE, N. Ireland, UK



**【Release date】** In October 2020

**【Version】** 05/2019-C1