# D-Dimer Test Reagent (LETIA)

**【Product Name】**

Product Name: D-Dimer Test Reagent (LETIA)

**【Packing Specifications】**

| | |
|---|---|
| Reagent | 40mL (R1:1×30mL + R2:1×10mL) |
| Calibrator | 6×0.5mL |
| Control | 2×0.5mL |

**【Intended Use】**

D-Dimer, a product for the detection of plasmin in plasma or serum to break down fibrin.

D-Dimer is a specific degradation product produced by plasmin hydrolysis after the crosslinking of fibrin monomer activation factor XIII, and is a specific marker of fibrinolysis process. D-Dimer is derived from plasmin-hydrolyzed cross-linked fibrin clots.

D-Dimer mainly reflects fibrinolytic function. As long as there is activated thrombosis and fiber dissolving activity in the body's blood vessels, D-Dimer will be elevated; D-Dimer is a key indicator of deep vein thrombosis (DVT), pulmonary embolism (PE), disseminated intravascular coagulation (DIC). D-Dimer is often used to assist in the diagnosis of obstetric diseases, vascular lesions and other diseases.

**【Inspection principle】**

In the reaction system, the D-Dimer in the sample and the anti-human D-Dimer latex particles in the reagent undergo agglutination reaction, and the agglutination reaction forms an antigen-antibody complex to produce turbidity, and its turbidity is proportional to the sample when a certain amount of antibody is present. By measuring the absorbance value at a specific wavelength, the amount of D-Dimer in the sample can be calculated by reference to the calibration curve.

**【Main components】**

| Composition | Main components |
|---|---|
| R1 | Tris buffer pH7.4 |
| | Sodium chloride |
| | PEG20000 |
| R2 | Anti-human D-Dimer latex granules |
| | ProClin 300 |
| Calibrator | D-Dimer |
| Control | D-Dimer |

**【Storage conditions and expiration date】**

The detection reagent is kept tightly closed at 2~8°C for 12 months; Store stable at 2~8°C for 30 days after opening.

The calibrator is stored in a closed and stable manner at 2~8°C for 12 months; Store stable at 2~8°C for 14 days after reconstitution.

**【Applicable Instruments】**

Applicable models of this reagent:

Hitachi 7600/7020/7060/7080/7180; The Beckman AU480/680 and other models have a fully automatic biochemical instrument with a wavelength of around 570nm.

**【Sample Requirements】**

Fresh and non-hemolytic plasma.

Samples 2 ~ 8 °C stored for one day.

Do not use samples that have been contaminated.

**【Inspection method】**

1. Reagent preparation: double reagents do not need to be formulated, directly used.
2. Test conditions: as shown in the following figure (different hands-on parameters can be requested according to different testing instruments)

| | |
|---|---|
| Wavelength | 700nm |
| Sample / R1 / R2 | 4 / 180 / 60 |
| Correction method | 6 points calibration |
| Correction type | Nonlinearity |
| Method | Two-point method |
| Reaction direction | Up |

3. Procedure:

| | |
|---|---|
| Sample | 4 μL |
| Reagent 1 (R1) | 180 μL |
| Mix well and incubate at 37°C for 5 min | |
| Reagent 2 (R2) | 60 μL |
| Mix well, after 10 sec of incubation, read the absorbance ($A_1$), after 5 minutes, read the absorbance ($A_2$), $\triangle A = A_2 - A_1$ | |

4. Calibration procedure:
   It is recommended to use the matching calibration product, multi-point calibration curve polyline processing, the same measurement method.
5. Quality control procedures:
   It is recommended to use the matching control to control the relative deviation within the performance indicators.
6. Calculation of test results:
   Multipoint calibration, using spline functions as a calculation mode to plot the standard curve, the D-Dimer content in the sample can be calculated on the standard curve according to its absorbance value.

**【Reference interval】**

The reference range was 0.5mg/L.

This range is for reference only and it is recommended that each laboratory establish its own range of reference values.

**【Interpretation of test results】**

1. When the D-Dimer>30mg/L in the sample, the sample should be diluted with normal saline n times, retested, and the test result multiplied by n to obtain the concentration in the original sample.
2. Hemolysis interferes with the measurement, and hemolysis should be avoided as much as possible during operation.
3. When used for diagnostic purposes, the results of this test should always be interpreted in conjunction with the patient's medical history, clinical symptoms and diagnosis and treatment results.
4. Measure the quality control products, and the results should be within the user's self-built control limits; If it is not in the range, it should be re-measured and confirmed, and analyzed, to find the cause.

**【Limitations of the test method】**

When bilirubin ≤ 300 μmol/L, triglycerides ≤ 10 mmol/L, ascorbic acid ≤ 2.8 mmol/L, hemoglobin ≤ 5.0 g/L, and rheumatoid factor ≤ 400 IU/mL, there was no significant effect on the measurement results.

The test results are for reference only and are not used as the sole basis for clinical diagnosis.

**【Product Performance】**

The following results were obtained by testing this reagent on the Hitachi 7080 automatic biochemical analyzer:

1. Reagent blank absorbance: A≤2.0(570nm, optical diameter 10mm, 37 °C);
2. Analytical sensitivity: When the concentration of D-Dimer in the sample is 1mg/L, the absorbance change value ΔA≥0.01.
3. Measurement precision: Intra-assay repeatability CV ≤8%, assay relative range R≤10%；
4. Accuracy: relative deviation≤ 10%;
5. Linear range: [0.2-30 mg/L], linear correlation coefficient r≥0.990;
   absolute value of absolute deviation in the range of [0.2-3 mg/L] ≤0.3 mg/L;
   In [3-30 mg/L], the absolute value of the relative deviation in the range ≤ 10%;
6. Method comparison: The D-Dimer content of 100 samples was determined by this reagent and imported reagents of the same method, and the results showed that the correlation coefficient r >0.98.

**【Precautions】**

1. This product is only used for in vitro diagnosis for the detection of plasma samples;
2. Avoid contact with skin, eyes and mucous membranes, once contacted, should rinse the contaminated part with water;
3. The volume of reagents and samples can be increased or decreased proportionally due to different instrument requirements, and the calculation formula remains unchanged;
4. The reagent should avoid contamination in use, otherwise it will lead to failure;
5. There will be differences between the quality control results of reagents in different methodologies, please ensure that the quality control selection is consistent with the methodology of the reagents when using;
6. The operation should be carried out in strict accordance with the instructions, and reagents with different batch numbers cannot be mixed;
7. The reagent contains substances of animal origin, originating from non-epidemic areas, and after inspection and quarantine, it is not excluded that it contains other unknown infectious substances, so it should be treated as infectious substances when used;
8. All samples should be regarded as potentially infectious substances, and the handling, use, storage and disposal of waste of each component of samples and kits should be handled in accordance with the corresponding measures of the national biohazard safety guidelines or procedures to ensure the safety of users and the environment during use.

# D-二聚体检测试剂盒使用说明书

（胶乳增强免疫比浊法）

【产品名称】

通用名称：D-二聚体检测试剂盒（胶乳免疫比浊法）

英文名称：D-Dimer Test Reagent (LETIA)

【包装规格】

| | |
|---|---|
| 试剂 | 40mL (R1:1×30mL + R2:1×10mL) |
| 校准品 | 6×0.5mL |
| 质控品 | 2×0.5mL |

【预期用途】

用于检测血浆或血清中的纤溶酶分解纤维蛋白的产物 D-Dimer。

D-Dimer 是纤维蛋白单体活化因子 XIII 交联后，再经纤维溶酶水解所产生的一种特异降解产物，是一个特异性的纤溶过程标记物。D-Dimer 来源于纤溶酶解的交联纤维蛋白凝块。

D-Dimer 主要反映纤维蛋白溶解功能。只要机体血管内有活化的血栓形成及纤维溶解活动，D-Dimer 就会升高；D-Dimer 是深静脉血栓(DVT)，肺栓塞(PE)，弥散性血管内凝血(DIC)的关键指标。测定 D-Dimer 常用于产科疾病、血管病变等疾病中的辅助诊断。

【检验原理】

在反应体系中，样本中的 D-Dimer 与试剂中抗人 D-Dimer 胶乳颗粒发生凝集反应，凝集反应形成抗原抗体复合物而产生浊度，其浊度高低在一定量抗体存在时与样品中成正比。通过测定特定波长的吸光度值，参照校准曲线即可计算出样本中 D-Dimer 的含量。

【主要组成成份】

| 组成 | 主要组份 |
|---|---|
| 试剂1 | Tris 缓冲液、聚乙二醇、氯化钠、防腐剂、表面活性剂 |
| 试剂2 | 抗人D-Dimer胶乳颗粒、稳定剂、防腐剂、表面活性剂 |
| 校准品 | D-Dimer、稳定剂、防腐剂、表面活性剂 |
| 质控品 | D-Dimer、稳定剂、防腐剂、表面活性剂 |

【储存条件及有效期】

1. 本试剂密闭贮存在 2～8℃避光条件下（勿冷冻），可稳定 12 个月。
2. 试剂 1 和试剂 2 开瓶后 2～8℃避光保存可稳定 30 天。
3. 校准品和质控品在 2～8℃密闭保存稳定 12 个月。

【标本要求】

1. 新鲜且不溶血血浆。
2. 溶血和浑浊等对吸光度有干扰的样本可能影响测定结果。

【适用仪器】

本试剂适用机型：日立 7600/7020/7060/7080/7180;贝克曼 AU480/680 以及其他型号具有 700nm 左右波长的全自动生化仪。

【检验方法】

1. 试剂配制：液体双试剂，无需配制，直接使用。
2. 操作参数

| | | | |
|---|---|---|---|
| 方法： | 终点法 | 反应时间： | 10 分钟 |
| 主波长： | 700nm | 副波长： | 无 |

| | | | |
|---|---|---|---|
| 样品量： | 4μL | 试剂量： | 180μL/60μL |
| 反应方向： | 正向 | 定标方式： | 多点非线性 |

3. 测定步骤

| | |
|---|---|
| 样本 | 4μL |
| 试剂 1（R1） | 180μL |
| 混匀，置于 37℃孵育 3min | |
| 试剂 2（R2） | 60μL |
| 混匀，37℃孵育 10 秒，读取第一点吸光度 $A_1$，5 分钟后读取第二点吸光度 $A_2$。计算$\Delta A= A_2- A_1$ | |

4. 校准程序

建议使用本公司配套的标准品多点定标曲线折线处理，测定方法同样本。

5. 质量控制程序

建议采用本公司配套的质控品，控制相对偏差在性能指标范围内。

6. 试验结果的计算

多点定标，以样条函数作为计算模式。根据吸光度与参考血清的值作剂量/响应曲线，样品含量可根据其吸光度值在剂量/响应曲线上算出。

【参考区间】

参考区间: ≤0.5μg/mL。

建议各实验室应根据地区及人群情况建立自己的参考区间。

【检验结果的解释】

1. 当样本中 D-Dimer 的浓度超过 30μg/mL 时，应将样本用生理盐水稀释后再测，测得的结果乘以稀释倍数。
2. 测定质控品，结果应在用户自建的控制限范围内;若不在范围内，应重新测定确认，并分析，查找原因。
3. 本质控品为非定值质控品，因此在实际应用中各实验室应根据不同的试剂盒不同的仪器来确实相应参考值。
4. 本质控品内所有值单或瓶签上的值为本公司日立 7080 测定的数据，仅供参考。

【检验方法局限性】

当样品中胆红素≤300μmol/L、甘油三酯≤10mmol/L、抗坏血酸≤2.8mmol/L、血红蛋白≤ 5.0g/L 、类风湿因子≤400IU/mL 时，对测定结果无显著影响；

检验结果仅供参考，不作为临床诊断的唯一依据。

【产品性能】

下面结果是用本试剂在日立 7080 全自动生化分析仪上测试获得的：

1. 试剂空白吸光度：A≤2.0（700nm，光径 10mm，37℃）；
2. 分析灵敏度：当样品中 D-Dimer 浓度为 1μg/mL 时，其吸光度变化值$\Delta$A≥0.01。
3. 测量精密度：批内重复性 CV ≤8%、批间相对极差 R≤10%；
4. 准确性：相对偏差≤10%；
5. 线性范围：0.2-30μg/mL，线性相关系数 r≥0.990；

a）在 0.2-3μg/mL 范围内的绝对偏差的绝对值≤0.3μg/mL；

b）在 3-30μg/mL，范围内的相对偏差的绝对值≤10%；

6. 方法比对：用本试剂与进口相同方法的试剂分别测定 100 例样本 D-Dimer 含量，结果显示相关系数 r >0.98。

【注意事项】

1. 本产品仅用于体外诊断，用于检测血浆样品；
2. 试剂避免接触皮肤、眼睛及粘膜，一旦接触，应即用水冲洗污染部位；
3. 试剂体积和样本体积可因仪器要求不同，按比例增减，计算公式不变；

4. 试剂在使用中应避免污染，否则将会导致失效；
5. 不同方法学试剂的质控结果之间会存在差异，使用时请确保质控选择与试剂的方法学保持一致；
6. 操作应严格按照说明书进行，不同批号的试剂不能混用；
7. 试剂中含有动物源性物质，来源于非疫区，并经检验检疫，不排除含有其他未知的传染性物质存在，因此在使用时应按传染性物质对待；
8. 所有样本均应视为具有潜在传染性物质，样本和试剂盒各组分的处理、使用、 储存及废弃物的处置，均应按照国家生物危害安全指南或规程的相应措施处理，确保使用过程中对使用者和环境的安全。