

# 乙肝丙肝艾滋病临床试验IVDR分类

产品名称	乙肝丙肝艾滋病临床试验IVDR分类
公司名称	国瑞中安集团-实验室
价格	.00/件
规格参数	
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## 产品详情

用于以下用途的器械归类为D类：

检测血液、血液成分、细胞、组织或器官，或其任何衍生物是否存在或显露传染性因子，以评估它们是否适用于输血、器官移植或细胞给药。

检测是否存在或显露传染性因子，其会导致危及生命的疾病，并且具有高的或可疑的传播风险。一确定危及生命的疾病的病原体载量，其监控对于患者管理的过程十分关键。

Devices used for the following purposes are classified as Class D:

To detect the presence or exposure of infectious factors in blood, blood components, cells, tissues or organs, or any derivatives thereof, to assess whether they are suitable for blood transfusion, organ transplantation or cell administration.

Detect the presence or exposure of infectious factors that can lead to life-threatening diseases and have a high or suspected risk of transmission. Once the pathogen load of life-threatening diseases is determined, its monitoring is critical to the process of patient management.

### 2.2, 规则2

器械预期用于血型分型或组织分型，以确保用于输血或移植或细胞给药的血液、血液成分、细胞、组织或器官具有免疫相容性，此类器械归类为C类，但用于确定以下任何标记物的器械除外：

- ABO 系统 [ A (ABO1)、 B (ABO2)、 AB (ABO3) ] ；

恒河猴(Rhesus)系统 IRHI (D)、 RHWL RH2 (C)、 RH3 (E)、 RH4 (C)、

RH5 (E) ] ;

— KELL 系统 [ Kell (K) ] ;

- KIDD 系统 UK1 (JKA)、JK2 (JKB) ] ;

— DUFFY 系统 [ FYI (FYA)、FY2 (FYB) ] ,

在这种情况下 , 它们被归为D类。

## 2.2, Rule 2

The device is intended to be used for blood typing or tissue typing to ensure that the blood, blood components, cells, tissues or organs used for blood transfusion or transplantation or cell administration have immunocompatibility. Such devices are classified as Class C, except for devices used to determine any of the following markers:

-ABO system [A (ABO1), B (ABO2), AB (ABO3)];

Rhesus monkey system IRHI (D), RHWL RH2 (C), RH3 (E), RH4 (C)

- KELL system [Kell (K)];

-KIDD system UK1 (JKA), JK2 (JKB)];

- DUFFY system [FYI (FYA), FY2 (FYB)],

In this case, they are classified as Class D.