

Количественное определение Д-димера (DDi)

Приготовление реагентов проводить в соответствии с инструкцией к набору.

Путь проверки (создания) протокола

[Menu] → [Setting] → [Assay Parameters] → [DDi] или [Red D-dimer] → [Test Protocol]

Тест можно создать путём копирования стандартного теста DDi.

The screenshot shows the 'Assay Group Setup' window with the 'Test Protocol' tab selected. The configuration is as follows:

- Assay Group:** Red D-dimer
- Display Name:** RDD
- Management ID:** 20035
- Valid:**
- Updated on:** 16/04/2010
- Assay Group Host ID:** 61
- Analysis Condition:**
 - Default Dilution Ratio:** 1/1
 - Replications:** 2
- Assay Parameter Table:**

Valid	Display Name	Assay Parameter	Updated on
<input checked="" type="checkbox"/>	RDDdOD	RDD dOD	14/04/2010
<input checked="" type="checkbox"/>	RDDCon	RDD Conc	14/04/2010

Buttons at the bottom include: Copy, Up, Delete, Down, Export, Add, Load, Print, Save, Close.

В настройках созданного теста перейдите на вкладку Test Protocol и проверьте введенные данные в соответствии с настройками, указанными ниже:

РеДимер-тест



Assay Group Setup

Assay Group: **Red_D-dimer**

Basic | Re-analysis | Reflex | QC | Test Protocol

Rinse at the Time of Primary Aspiration: Pre-Rinse Post-Rinse

Sample Dispensing/Dilution

Dilution Setting

Buffer: **DD Diluent** Dilution Ratio for Measurements: **1/1, 1/2, 1/4, 1/8, 1/16, 1/32**

Aspirated Sample	Sample Aspiration Vol. [uL]	Buffer Volume [uL]	Pre-Rinse List	Post Rinse List
Sample	10	10	-	Clean I

Factor-Deficient Plasma

Aspirated Reagent	Reagent Aspiration Vol.[uL]	Pre-Rinse List	Post Rinse List

Reagent Protocol

Aspirated Reagent	Reagent Aspiration Vol.[uL]	Pipette at [sec]	Mixing Level	Pre-Rinse List	Post-Rinse List
DD RBuff	80	20	Middle	-	Clean I
DD Latex	80	90	Middle	-	Clean I

Measurement Condition

Measurement Time (Main): **200** sec Measurement Time (Sub): **200** sec

Measurement Time (Main) | Measurement Time (Sub)

Mixing during measurement

STEP1: **0** sec - **0** rpm

STEP2: **0** sec - **0** rpm

STEP3: **0** sec - **200** sec **0** rpm

Seq.	Reagent	Lot Manag	Stable Time
1	DD Diluent	<input type="checkbox"/>	0
2	DD RBuff	<input type="checkbox"/>	0
3	DD Latex	<input type="checkbox"/>	0

Вернитесь во вкладку Basic для проверки и редактирования настроек теста. Переходите по вкладкам Calculation Method\ Datacheck\ Evaluation Preset для проверки всех настроек.



Assay Parameter Setup

Assay Parameter: Display Name: Management ID:

Valid Updated on: Assay Parameter Host ID:

Calculation Method | Data Check | Evaluation Preset

Raw Data Unit System: Units: Digits: Integral Part Decimal Part

Calib. Curve Unit System: Units: Digits: Integral Part Decimal Part

Input Value: Calib. Curve Type: Interpolation Method: Auto Origin Generation

Axis
X Axis: Y Axis:

Extrapolation
 Extrapolate Range: Min. X - Max. X

Graph Axis
X Axis Min.: X Axis Max.: Y Axis Min.: Y Axis Max.:

Dilution Analysis:

Correction	Calibrator	Dilution Ra	Replicatio	Stable Time



РеДимер-тест

Assay Parameter Setup

Assay Parameter: Display Name: Management ID:

Valid Updated on: Assay Parameter Host ID:

Calculation Method: Evaluation Preset:

Report Limit Check

Upper Limit: Lower Limit:

Mark Limit Check

Upper Limit: Lower Limit:

Replication Difference Limit Check

Upper Limit:

MDA Slope Ratio Check

Upper Limit: Lower Limit:



Assay Parameter Setup

Assay Parameter: Display Name: Management ID:

Valid Updated on: Assay Parameter Host ID:

Calculation Method | Data Check | Evaluation Preset

Evaluation Algorithm: Detection Principle:

Target

Wave:

Type:

Gain:

Smoothing

Reference Correction

Median Preceding Point: Following Point:

Moving Average Preceding Point: Following Point:

Correction

User

A (Slope) B(Offset)

Evaluation Parameter | **Evaluation Check Parameter**

Start Time[sec]: Polynomial Dimension:

End Time[sec]: Integral Area(auc):

Min. Regression Time[sec]:

Variable Start Time

Preeval Search Width[sec]:

Upper Eval Offset[sec]:

Upper Preeval Rate[dOD/min]:

Lower Preeval Rate[dOD/min]:

Minimum Search Window[sec]:



Assay Parameter Setup

Assay Parameter: RDD dOD Display Name: RDDdOD Management ID: 20035

Valid Updated on: 14/04/2010 Assay Parameter Host ID: 1

Calculation Method | Data Check | Evaluation Preset

Evaluation Algorithm: VLin analysis Detection Principle: Immunoassay Method

Target
Wave: 800nm
Type: Transmitted
Gain: Low

Smoothing
 Reference Correction
 Median Preceding Point: 5 Following Point: 5
 Moving Average Preceding Point: 5 Following Point: 5

Correction
 User
A (Slope) B (Offset)
1.00 0.0000

Evaluation Parameter Evaluation Check Parameter

High Light Limit: 4000
Low Light Limit: 200

Reaction Curve
Slope: Increase
Slope Thresh.: 0.0010

Antigen Check
Start Time 1[sec]: 3.0
End Time 1[sec]: 11.0
Cut Off: 0.0270
Rate: 7.0000
Offset: -0.0400
Start Time 2[sec]: 70.0
End Time 2[sec]: 150.0

Save Close

Выберите соответствующие разведения плазмы-калибратора для построения калибровочного графика



Assay Parameter Setup

Assay Parameter: Display Name: Management ID:

Valid Updated on: Assay Parameter Host ID:

Calculation Method | **Data Check** | Evaluation Preset

Raw Data Unit System: Units: Digits: Integral Part Decimal Part

Calib. Curve Unit System: Units: Digits: Integral Part Decimal Part

Input Value: Calib. Curve Type: Interpolation Method: Auto Origin Generation

Axis
X Axis: Y Axis:

Extrapolation
 Extrapolate Range: Min. X - Max. X

Graph Axis
X Axis Min.: X Axis Max.: Y Axis Min.: Y Axis Max.:

Dilution Analysis:

Correction	Calibrator	Dilution Ra	Replicatio	Stable Time
<input type="checkbox"/>	DD Cal	1/1	2	0
<input type="checkbox"/>	DD Cal	1/2	2	0
<input type="checkbox"/>	DD Cal	1/4	2	0
<input type="checkbox"/>	DD Cal	1/8	2	0
<input type="checkbox"/>	DD Cal	1/16	2	0
<input type="checkbox"/>	DD Cal	1/32	2	0



РеДимер-тест

Assay Parameter Setup

Assay Parameter: Display Name: Management ID:

Valid Updated on: Assay Parameter Host ID:

Calculation Method | Data Check | Evaluation Preset

Report Limit Check

Upper Limit: Lower Limit:

Mark Limit Check

Upper Limit: Lower Limit:

Replication Difference Limit Check

Upper Limit:

MDA Slope Ratio Check

Upper Limit: Lower Limit:

Save Close



Assay Parameter Setup

Assay Parameter: Display Name: Management ID:

Valid Updated on: Assay Parameter Host ID:

Calculation Method | Data Check | Evaluation Preset

Evaluation Algorithm: Detection Principle:

Target
Wave:
Type:
Gain:

Smoothing
 Reference Correction
 Median Preceding Point: Following Point:
 Moving Average Preceding Point: Following Point:

Correction
 User
A (Slope) B(Offset)

Evaluation Parameter | **Evaluation Check Parameter**

Start Time[sec]: Polynomial Dimension:
End Time[sec]: Integral Area(auc):
Min. Regression Time[sec]:
 Variable Start Time
Preeval Search Width[sec]:
Upper Eval Offset[sec]:
Upper Preeval Rate[dOD/min]:
Lower Preeval Rate[dOD/min]:
Minimum Search Window[sec]:



Assay Parameter Setup

Assay Parameter: RDD Conc Display Name: RDDCon Management ID: 20035

Valid Updated on: 14/04/2010 Assay Parameter Host ID: 2

Calculation Method | Data Check | Evaluation Preset

Evaluation Algorithm: VLin analysis Detection Principle: Immunoassay Method

Target
Wave: 800nm
Type: Transmitted
Gain: Low

Smoothing
 Reference Correction
 Median Preceding Point: 5 Following Point: 5
 Moving Average Preceding Point: 5 Following Point: 5

Correction
 User
A (Slope) B (Offset)
1.00 0.0000

Evaluation Parameter Evaluation Check Parameter

High Light Limit: 4000
Low Light Limit: 200

Reaction Curve
Slope: Increase
Slope Thresh.: 0.0010

Antigen Check
Start Time 1[sec]: 3.0
End Time 1[sec]: 11.0
Cut Off: 0.0270
Rate: 7.0000
Offset: -0.0400
Start Time 2[sec]: 70.0
End Time 2[sec]: 150.0

Save Close

Сохраните все внесенные настройки и выполните стандартные операции по калибровке соответствующей методики, а также, проведению контроля качества (при помощи контрольных материалов РеДимер контроль Д-2) перед выполнением анализа пациентов.

Условия переразведения: желательно установить переразведение анализируемых образцов при получаемых результатах свыше 3,5 мг\л (FEU) по аналогии с настройками стандартного теста для количественного определения Д-димера.

