



## IntelliPlex™ Calibration Kit



80035

1 Piece



For In Vitro Diagnostic Use



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### European Authorized Representative:



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**IMPORTANT:**  
 Read the instructions carefully prior to use

### 1. INTENDED USE

The IntelliPlex™ Calibration Kit is designed to calibrate the output fluorescence signal of the analyzers. Based on 8 concentrations of solid phase reference signals, the algorithm embedded in DeXipher™ will use linear regression to calibrate the Median Fluorescent Intensity (MFI) output within the defined range.

### 2. INTRODUCTION

Fluorescent dye is embedded in a porogen free block polymer. The polymerization reaction is carried out in wells of a 96-well plate so that the resulting polymers are fitted inside the well, creating a solid, stable block that stably molded in the well. Since the fluorescent is located in a solid, dry environment, making it very stable with long shelf life. This product is expected to be re-usable and, once calibrated by a reference fluorescent standard, be used as a long term QC tool for any fluorescence plate reader. The coefficient of variation (CV) of the calibration could be less than 5%.

Software can automatically identify the kit and the wells with different concentration based on the lot number. There is no need to enter concentration or kit info in user interface (UI).

### 3. WARNINGS AND PRECAUTIONS

- For in-vitro diagnostic use.
- This assay kit should be used by qualified laboratory personnel only.
- Do not use a kit past its expiration date.
- Do not attempt to fill reference standard well with any liquid solution.
- Store the kit and the plate in the dark at 15-35°C according to the product label and instructions.
- Wear powderless gloves and do not touch and make any markings on the bottom of the plate at any time, as fingerprints and markings would interfere with decoding and signal acquisition.
- General laboratory precautions should be taken:
  - Do not pipette by mouth.
  - Wear protective clothing (e.g., disposable powderless gloves and laboratory coats) and eye protection.
  - Do not eat, drink or smoke in the laboratory.
  - Wash hands thoroughly after handling samples and reagents.
- Safety Data Sheets (SDS) are available upon request from PlexBio Customer Service.

### 4. KIT COMPONENT OVERVIEW

The IntelliPlex Calibration Kit contains one 96-well plate and one user manual. The column 6 and 7 indicate the MFI output from high to low. Each column is replications of the reference signal. The column 1 and 2 are used to control and identify the serial number of the calibration kit through the software automated recognition.

### 5. MATERIALS AND EQUIPMENT REQUIRED BUT NOT SUPPLIED

- Disposable gloves, powder-less
- PlexBio 100 Fluorescent Analyzer (PlexBio; Cat. No. 80000)

### 6. STORAGE, STABILITY AND TRANSPORTATION

The IntelliPlex Calibration Kit should be kept in the dark at 15~35°C. The shipping temperature for the calibration kit is under the room temperature. Do not use the IntelliPlex Calibration Kit after the expiration date. The plate is guaranteed up to the expiration date on the label if handled and stored under the recommended

conditions.

## 7. INSTRUMENT AND SOFTWARE

### Instrument

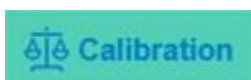
Refer to the instrument user manual for complete operation instructions.

### Software Installation

**NOTE before Assay Starts:**

- Visit [www.plexbio.com](http://www.plexbio.com) and download the IntelliPlex Calibration Kit ENC file. Each kit will have a unique ENC file, so you will need to download a new ENC file each time you purchase a kit. Make sure to select the ENC file with the lot and serial number that correspond to your kit.

- Click on the button as shown below on the DeXipher homepage.



- Click on the button as shown below to import kit.



- Select the corresponding ENC file.
- Open the ENC file to import into the software.

## 8. CALIBRATION PROCEDURE

**Warning:**

*Read the instructions carefully and follow every step of the assay protocol correctly.*

- Place the plate on the Analyzer.
- Click on the icon button as shown below for the signal calibration.



- After the reading is done, calibration results will be displayed on the right side.

## 9. TROUBLESHOOTING

The troubleshooting guide listed below addresses possible problem causes and solutions provided during assay procedures.

Problem	Possible Cause	Recommendations
Calibration Fail	1. Wrong ENC file. 2. The kit is expired. 3. The instrument is out of order.	1. Make sure the ENC file is imported into DeXipher which matches the serial no. of the kit. 2. Make sure the kit is not expired. 3. Please contact PlexBio Customer Service.

## 10. SYMBOLS

Symbol	Explanation	Symbol	Explanation
	In-vitro diagnostic use		Catalog number
	Serial number		Consult instructions for use
	Manufacturer		Use by Date
	Temperature limitation		Caution
	Manufacture Date		Batch number
	European Union Conformity		European Authorized Representative



## 11. REFERENCES

Extending Linear Regression: Weighted Least Squares, Heteroskedasticity, Local Polynomial Regression 36-350, Data Mining 23 October 2009.

**Notice to User**

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