



LIFECODES®

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Product Documentation and Translations available at: www.Immucor.com

PRODUCT INSERT

LIFECODES® Taq Polymerase for use with LIFECODES HLA-SSO TYPING KITS
For In Vitro Diagnostic Use

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DEFINITION OF SYMBOLS (Product Labels and Supplemental Documents)

| | | | | | | | |
|------------------------------------|--|------------------------------|--|---|--|------------------------------------|--|
| Batch Code | | Catalog Number | | Temperature Limitation | | Unique Device Identification | |
| Use By Date | | Importer | | Sufficient for N Tests | | In Vitro Diagnostic Medical Device | |
| Caution – See instructions for Use | | Consult Instructions for Use | | Authorized Representative in the European Community | | | |

REAGENT BY CATALOG NUMBER

| Reagent | Product Number | Fill volume | Storage | CE |
|-------------------------------------|----------------|-------------|----------------|----|
| TAQ LIFECODES Taq Polymerase | 628075 | 25 µL | -10°C to -30°C | |

INTENDED USE

Taq Polymerase is an additional accessory reagent solely for use with the following products for use in amplification of DNA step, which are specific to the qualitative manual assay products below:

[LIFECODES HLA-AeRES SSO Typing Kits \(628913\)](#)
[LIFECODES HLA-BeRES SSO Typing Kits \(628917\)](#)
[LIFECODES HLA-CeRES SSO Typing Kits \(628921\)](#)
[LIFECODES HLA-DRB1eRES SSO Typing Kits \(628925\)](#)
[LIFECODES HLA-DRB3,4,5 SSO Typing Kits \(628927\)](#)
[LIFECODES HLA-DQA1/B1 SSO Typing Kits \(628930\)](#)
[LIFECODES HLA-DPA1/B1 SSO Typing Kits \(628936\)](#)

SUMMARY AND EXPLANATION

Taq Polymerase is a DNA polymerase used in the amplification of DNA (PCR). DNA-based HLA typing using PCR amplified DNA is a common laboratory procedure. PCR amplification of DNA is used as the means to enrich for a selected DNA region. For HLA typing, a subsequent assay is utilized to determine the properties of the amplified DNA. Several types of assays, such as SSP (1), direct SSOP (2), RFLP (3) and reverse SSOP dot blot technologies (4), have been used in HLA typing. Like SSOP and reverse dot blot methods, LIFECODES HLA-SSO Typing Kits utilize sequence-specific oligonucleotides (SSOs) to identify which HLA alleles are present in a PCR amplified sample. It is the set of SSOs employed, not the methodologies, that determines the ability to distinguish among the various alleles present in the PCR amplification. Whereas reverse dot blot and SSOP methods employ enzyme labels and colorimetric substrates that require subsequent development, the LIFECODES assay is a homogenous multiplex system. That is, all SSOs are analyzed simultaneously and the entire assay is carried out in a single reaction vessel with the addition of a single reagent.

REAGENT INFORMATION

A. Warnings and Cautions

1. For In Vitro Diagnostic Use with LIFECODES HLA SSO Typing Kits only
2. Results from these kits are not to be used as the sole basis upon which a clinical decision affecting the patient is made
3. Taq Polymerase contains hazardous compounds. Avoid contact with skin and eyes and dispose of all materials after use according to local regulations. See Material Safety Data Sheets for additional information
4. LIFECODES Taq polymerase has been validated for use with LIFECODES HLA SSO typing Kits. Deviations from recommended protocol and materials have not been validated

B. Storage Instructions

Store at -10 to -30°C. Do not use components past their expiration date

C. Purification or Treatment Required for Use

None

DIRECTIONS FOR USE

Each vial contains 25µL of Taq polymerase at 5U/µL.

Refer to Product Insert for LIFECODES HLA SSO Typing Kits LC1436VDEN for additional information.

LIMITED LICENSES

Taq polymerase is manufactured for Immucor GTI Diagnostics by Promega Corp. It is licensed to Promega under U.S. Patent Nos. 5,338,671 and 5,587,287 and their corresponding foreign patents.

AUTHORIZED REPRESENTATIVE

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TRADEMARKS USED

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Luminex® Luminex Corporation

Key: Underline = Addition or significant change;
▲ = Deletion of text

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