

Declaration of Conformity

We NovaTec Immundiagnostica GmbH
Waldstraße 23 A6
63128 Dietzenbach
Germany

herewith declare under our own responsibility, that the product

NovaLisa® Herpes simplex Virus 2 (HSV 2) IgG (HSV2G0540)

and the following components:

| | |
|---------------------|----------------------------|
| MTP | Microtiterplate |
| DIL G | IgG Sample Dilution Buffer |
| SOLN STOP | Stop Solution |
| WASH BUF 20x | Washing Buffer (20x conc.) |
| CONJ | Conjugate |
| SUB TMB | TMB Substrate Solution |
| CONTROL - | Negative Control |
| CUT OFF | Cut-off Control |
| CONTROL + | Positive Control |

is in accordance with the requirements of the IVD Directive 98/79/EC of the European Parliament and Council of Oct. 27, 1998 in regard to in vitro diagnostic medical devices (IVDs).

The accordance was shown by conformity assessment procedures in
Annex III (2-5)

Dietzenbach 2020.07.22


Jennifer Völger
Quality Management Representative

The conformity of the above mentioned product is checked at least every 3 years. This is documented by rechecking and signing the general requirements.