

### Application

The ImmuLex™ *H. influenzae* products are for serotyping either *H. influenzae* serotype a, b, c, d, e or f separately or in a polyvalent pool.

### Description

The ImmuLex™ *H. influenzae* contains a vial with latex particles coated with one of the *H. influenzae* serotypes or a polyvalent antiserum raised in rabbits (0.0975 % sodium azide as preservation). The vial contains reagent for approximately 75 tests.

### Principle

The ImmuLex™ *H. influenzae* provides a rapid ready-to-use latex agglutination test for typing of *H. influenzae* serotypes.

### Performance

Two studies were conducted at the reference laboratory in Copenhagen, Denmark. The first study consisted of 120 *H. influenzae* strains (43 serotype b and 77 other serotypes or non-capsulated strains), all of which were tested in ImmuLex™ *H. influenzae* serotype b. The results showed that all 43 serotype b strains were detected by ImmuLex™ *H. influenzae* serotype b, and there were no cross-reactions to the other *H. influenzae* serotypes. The second study consisted of 74 *H. influenzae* strains, which were tested in all seven ImmuLex™ *H. influenzae* products. The result of the study is shown in the table below. Furthermore, the reference laboratory examined 22 non-capsulated strains, and no cross-reactions were detected.

Number of Isolates	<i>H. influenzae</i> serotype	Number of positive reactions						
		a	b	c	d	e	f	Polyvalent
10	a	10	0	0	0	0	0	10
6	b	0	6	0	0	0	0	6
4	c	0	0	4	0	0	0	4
4	d	0	0	0	4	0	0	4
15	e	0	0	0	0	15	0	15
12	f	0	0	0	0	0	12	12

### Limitations

The ImmuLex™ *H. influenzae* products have not been tested directly on human specimens and are only intended for serotyping of a pure *H. influenzae* culture.

### Materials Required but not Provided

- Chocolate agar plate
- Phosphate buffered saline (pH 7.4)
- 1 µL inoculation loop
- Disposable reaction cards (200 pcs. art. no. 53285)

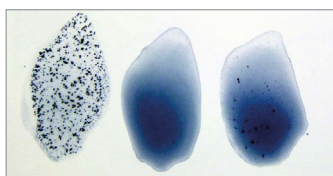
### Procedure

Do not perform more than 3 reactions simultaneously before reading the result.

1. The *H. influenzae* culture should be incubated overnight on a chocolate agar plate.
2. Before use of the latex reagent it is very important to bring the bottles to room temperature and shake.
3. For each reaction set of a drop of approx. 10 µL (squeeze the bottle gently) of latex reagent on to the reaction card.
4. Suspend a colony from a chocolate agar plate in 200 µL phosphate buffered saline\*.
5. Add 10 µL of this bacterial suspension to the reaction card.
6. Mix the two drops with a mixing stick. Use a separate stick for each reaction.
7. Spread to cover the area of the circle.
8. Rock the card slowly and observe for agglutination within 20 seconds. Any agglutination after 30 seconds is not a positive reaction.

\* It is important **not** to use too much culture and to avoid material from the agar plate as this may lead to false positive reactions.

### Interpretation of Results



The figure shows three reactions. From left to right: Circle 1 is a positive reaction, and circle 2 and 3 are both negative reactions. Although circle 3 shows some granules, this is not a true positive reaction.

### Storage and Shelf Life

Store at 2-8 °C in a dark place. Do not freeze (if the reagents have accidentally been frozen, they should not be used).

### Information and ordering

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