PRECAUTIONS

1. Reagents are for IN VITRO DIAGNOSTIC USE ONLY.
2. Do not use reagents after expiry date shown on product label.
3. Conjugate and antigen reagents contain 0.1% sodium azide. Sodium azide can react explosively with lead or copper if allowed to accumulate. Although the amount of sodium azide in the reagents is minimal, large quantities of water should be used when flushing used reagent down the sink.
4. Patient specimens and culture isolates should be considered potentially infectious and precautions appropriate to microbiological hazards must be observed.
5. Process slides individually and avoid cross-contamination with staining reagents.
6. Never allow staining reagent to dry on the slide during staining procedure.

INTERPRETATION OF RESULTS

1. The following criteria must be met for a test to be valid.
   a. Staining MUST be at least 3+ with typical morphology for a bacillus to be scored as positive.
   4+ = brilliant yellow-green cell wall staining.
   3+ = bright yellow-green cell wall staining.
   2+ = diffusely stained cell wall.
   1+ = dim yellow-green staining of cell wall.
   b. The DFA reagent conjugate used in the test must produce 3+ to 4+ staining with the Positive Control antigen.
   c. The negative control must not react with the DFA reagent.
2. If all of the criteria in section 1 above are met, evaluate test results as follows:
   a. Brightly fluorescing bacilli (3+ or stronger): report as FA positive.
   b. No brightly fluorescing bacilli: report as FA negative.

LIMITATIONS OF THE PROCEDURE

1. The DFA test is presumptive for the identification of Legionella pneumophila serogroups 1 to 14. A positive result should be confirmed by assessment of growth requirements and biochemical techniques for Legionella bacteria.
2. A negative DFA test does not preclude the presence of Legionella other than those for which the isolate has been tested.
3. Mixed cultures containing species or serogroups of Legionella other than those for which the isolate has been tested along with small numbers of other species may also give negative results if the quantity of the latter is very low. Use of isolates derived from single colonies can reduce the likelihood of this occurrence.
4. The use of these reagents directly with patient specimens or for preparations other than those described in this kit is not recommended.
REFERENCES

= Use by
LOT = Lot number
! = Attention, see instructions for use
REF = Catalogue number
= Manufacturer
EC REF = Authorized Representative in the European Community
= Contains sufficient for <n> tests
IVD = In vitro diagnostic medical device
= Temperature limitation
= Consult instructions for use