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<b>MEDWISS Analytic GmbH</b>	<b>AllergyScreen/ AlleisaScreen</b>	Date 14.12.2016

## **Circular letter 13: Effects on the AllergyScreen/AlleisaScreen results by the use of contaminated solutions**

### **Background and Procedure**

The aim of this review is to prove, if contaminated solutions have any influence on the results of the AllergyScreen/AlleisaScreen system. Contamination of solutions can appear in case that the tip is not changed during the processing and two or more different solutions are pipetted with the same tip. Therefore, 4 ml of streptavidin-conjugate were mixed with 1 ml of detection antibody to imitate a strong contamination of streptavidin-conjugate with residual detection antibody. Additionally, 4 ml of substrate were mixed with 1 ml of streptavidin-conjugate to imitate a strong contamination of substrate with streptavidin-conjugate.

Using a positive serum (PS), two test strips were worked-off with “contaminated” streptavidin-conjugate, “contaminated” substrate and with both contaminated solutions, respectively. As references two test strips were worked-off using the same solutions but without any contamination. For analysis of the effect on the background, visual evaluation was performed after drying the membranes. Subsequently, test strips were scanned. The sum of allergy classes and the mean values were calculated.

### **Material**

P30 Food Iraq M-150526

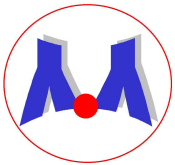
D-161107

S-161104

F-12342151

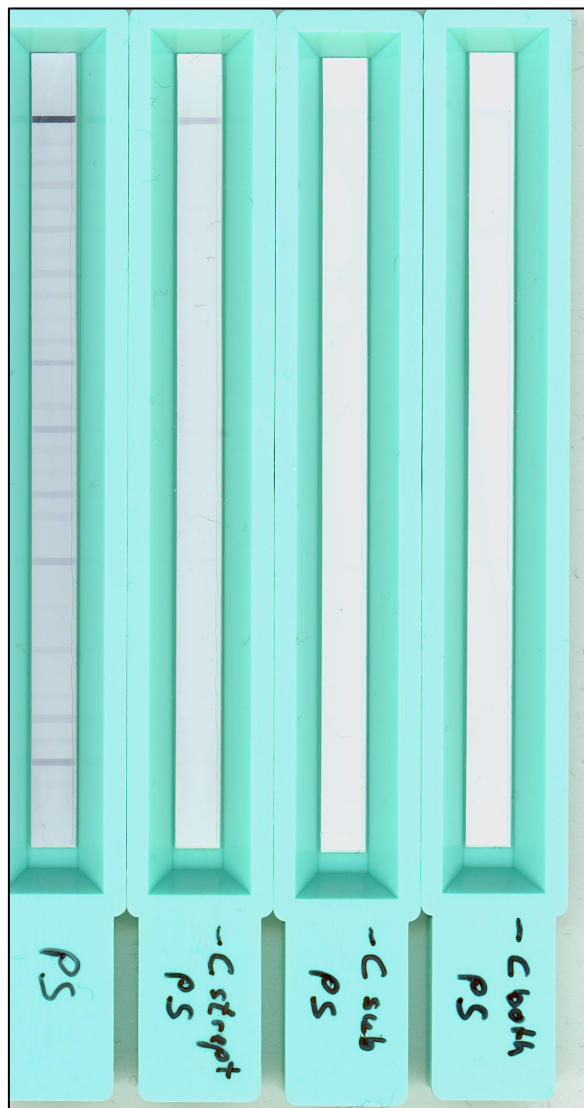
W-160609

PS

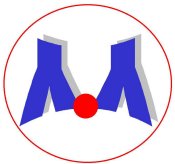
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**Results/ Observations**

The reference strip processed with PS serum shows many positive allergen lines with values of up to class 3.2 (test strip PS; Fig. 1). The value of the control line was class 6 as expected. When the streptavidin-conjugate, the substrate or both solutions were contaminated, no positive allergen lines were detected. The value of the control line was class 2.9 for contaminated streptavidin-conjugate. When the test strip was processed with contaminated substrate or with contaminated streptavidin-conjugate and contaminated substrate, no control line could be detected and the test was invalid.



**Fig.1:** Membranes were processed with and without contaminated solutions. From the left to the right: PS: reference test strip processed with serum PS and clean solutions; -C strept PS: test strip processed with serum PS with contaminated streptavidin-conjugate treatment during processing; -C sub PS: test strip processed with serum PS with contaminated substrate treatment during processing; -C both PS: test strip processed with serum PS with contaminated streptavidin-conjugate and contaminated substrate treatment during processing.

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**Tab.1:** Values of the control lines and mean values of the sum of allergy lines from the processed test strips (see Fig. 1)

Strip	Control line (class)	Sum of allergy lines (class)
<b>PS</b>	6,0	34,4
<b>PS contaminated streptavidin</b>	2,9	0,2
<b>PS contaminated substrate</b>	Test invalid – no control line	0,1
<b>PS contaminated streptavidin and substrate</b>	Test invalid – no control line	0,0

#### Background Analysis:

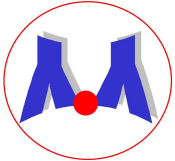
The background of the test strips treated with the contaminated solutions is much brighter compared to the background of the reference strip.

#### **Conclusion**

Contamination of solutions can appear in case that the tip is not changed during processing and two or more solutions are pipetted with the same tip. This can lead to a carryover for example of the detection antibody into the streptavidin-conjugate solution and the streptavidin-conjugate solution into the substrate, respectively.

This study shows that contaminated streptavidin-conjugate and contaminated substrate lead to a strong reduction or even a complete extinction of the control line and the allergen lines, respectively. This means that a carryover of a solution into the next may lead to false-negative results, which might lead to fatal conclusions. The reason for this is that the biotin of the detection antibody reacts with the streptavidin of the conjugate in the vial and no more free streptavidin is available for the reaction in the test trough.

A contamination of the substrate by the conjugate leads to a precipitation of the reactive substrate in the vial and no more substrate is available for the enzymatic reaction in the test trough.

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The contamination of both reagents (conjugate and substrate) leads to a complete blocking of the whole reaction.

### **Attention:**

**The tip of the pipette has to be changed for each solution; otherwise there will be no trustable result of the AllergyScreen/AlleisaScreen test system, because of contaminated solutions.**

**Also, any kind of contamination of the solutions has to be always avoided!**

**Small amounts of contamination in the vials and dropping bottles, leads to a continuously decline of reactivity of the used solutions in the test kit.**