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False-positive of blood culture instrument: leukocytosis, overfilled vials or defective position?

Faux positifs des incubateurs automatisés d'hémoculture : hyperleucocytose, flacons trop remplis ou alvéole défectueuse ?

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Abstract. Continuous monitoring of the performances of blood culture instrument can be based on the indicators proposed by the QUAMIC. Of these, the analytic performance indicator evaluates the rate of false-positive vials. False-positives vials can be reported by the device in case of leukocytosis or when vials are overfilled. In our laboratory, we record prospectively in our software all false positive vials as well as the position used for their incubation. These data are analyzed at least twice a year. For the first half of 2016, this strategy allowed us to identify a defective position. We then evaluated the impact of this anomaly as very weak. The one-year follow-up after the position repair confirmed a correction of the problem. Thus, traceability of positions reporting unexplained false-positive vials (i.e. neither due to leukocytosis nor overfilled vials) can allow laboratories to identify a defective position. This survey, if done prospectively, is simple to perform and not time-consuming. It could usefully complement the analytical performance indicator based on the false-positive rate.

Key word: *blood culture, false-positive vials, defective position, Bactec*

Résumé. Le suivi des performances en continu des incubateurs automatisés d'hémoculture peut s'appuyer sur les indicateurs proposés par le QUAMIC. Parmi ceux-ci, l'indicateur de performance analytique est basé sur le taux de faux positif de l'automate. Les faux positifs sont généralement dus à une hyperleucocytose majeure ou si les flacons sont trop remplis. Pour le suivi de cet indicateur, nous traçons prospectivement dans notre logiciel de laboratoire tous les flacons faux positifs ainsi que le numéro de l'alvéole dans laquelle le flacon était incubé. Ces données sont analysées à fréquence biannuelle *a minima*. En 2016, ce recueil nous a permis d'identifier une alvéole défectueuse. Une analyse de cette anomalie nous a permis d'écarter tout impact sur les résultats précédemment rendus. Le suivi à 1 an de la réparation de l'alvéole a montré une correction du problème. Ainsi, la traçabilité des alvéoles à l'origine du signalement d'un flacon faux positif inexpliqué (flacon correctement rempli en dehors de toute hyperleucocytose majeure) peut être mise à profit pour identifier une alvéole défectueuse. Cette traçabilité est simple à réaliser au quotidien. Elle pourrait compléter l'indicateur de performance analytique reposant sur le taux de faux positifs.

Mots clés : *hémoculture, flacon faux positif, alvéole défectueuse, Bactec*

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Monitoring the performance of automated system for the incubation of blood culture vials has many singularities. Indeed, the system comprises several separate positions for the incubation of each vial which makes difficult to evaluate their performances. In addition, some devices displayed a sensor that can detect a defective position. Thus, performing internal and external quality control using vials inoculated with reference strains allows only the specific control of some positions and the software of the instrument. The QUAMIC provides a simple and relevant solution in order to verify in continuous the performance of blood cultures instrument [1]. The management of indicators allows the laboratories to evaluate the pre-analytical, analytical and post-analytical steps of the process. Of these, the analytical specificity is based on the evaluation of the rate of false-positive vials. According to the supplier of our Bactec FX400 (Becton Dickinson, Franklin Lakes, New Jersey, USA), false positives vials can be reported by the device in case of leukocytosis and consequently if the vials are overfilled [2]. Considering previous report, we accept a maximum rate of false-positive vials of 1% [3-5].
In the present study, we propose to share our experience, which from the analytic specificity indicator, allowed us to identify a defective position of our Bactec FX400.

Material and methods

The rate of false-positive vials incubated in the Bactec FX400 of the laboratory of the Melun hospital is analyzed each semester since January 2016. Each vials considered as a false positive of the Bactec FX400 and the position used for its incubation are prospectively registered in our laboratory software.
Vials reported positive by the instrument were considered as false positives if:

– a Gram stain of the blood culture broth was negative for any microorganisms;
– the subculture of the blood culture broth on agar media was negative after 5 days of incubation. All blood culture broth was plated on a chocolate agar incubated in a 5% CO_2 enriched atmosphere at 35°C. Anaerobic vials were also inoculated on a Columbia agar plate enriched with 5% sheep blood and incubated at 35°C in an anaerobic atmosphere.
For each false positive vial, we collected the leucocytes count performed within at most 48 hours preceding or following the sampling of the vial.

Results

Identification of a defective position

During the first half of 2016, 6,749 vials were incubated in the Bactec FX400, of which 18 (0.27%) were false positives. This rate was consistent with our goal. The false-positive vials were incubated in six different positions (*table 1*):
– four positions reported a single false positive vial;
– one position reported two false positives vials;
– one position, No. 01-A-F03, reported twelve false positives vials, i.e. two-third of all false positives' vials for the period. The median leucocyte count of patients displaying a false positive vial incubated in this position was 9.12 / µL [5.51–13.47].
The position No. 01-A-F03 was inactivated and the supplier was requested for an intervention. He concluded to a deficiency of the position which was repaired.

Impact assessment

A vial wrongly reported as positive by the instrument has its incubation time shortened. Consequently, bacteremia

Table 1. Position used for the incubation of a false positive vials in 2016 and 2017.

First half of 2016		Second half of 2016		First half of 2017	
No. of position	**Number of vials**	**No. of position**	**Number of vials**	**No. of position**	**Number of vials**
01-A-G07	1	01-A-A08	1	01-A-J10	1
01-A-D07	1	01-A-F02	1	01-B-C05	1
01-A-F03	**12**	**01-A-F03**	**1**	01-B-C08	1
01-A-F07	2	01-A-A05	1	01-B-K05	1
01-B-H02	1	01-A-G10	1	01-C-D10	1
01-B-E05	1	01-C-B08	1	01-D-C05	1
		01-C-J03	1	01-D-E04	1
		01-D-E02	1		
		01-D-G06	2		
		01-D-A07	1		
		01-D-B10	1		

Position No. 01-A-F03 is in bold.

might not be identified. This risk can be controlled by the systematic subculture of the blood culture broth. In addition, except for pediatric patients, the collection of blood culture generally includes four vials. The risk that all of them are incubated in defectives positions is very small regarding the robustness of the Bactec FX400 and the low incidence of defectives positions. Furthermore, no pediatric flask incubated in cell No. 01-A-F03 was considered as a false positive.
Conversely, it is possible that this position may generate false negatives results, which would also lead to overlooking a bacteremia. A simple solution would be to evaluate the rate of positive vials per position which is not possible with the Bactec FX400. Nevertheless, according to the supplier, the abnormality of position No. 01-A-F03 led to inadvertent signaling of positivity, but not to false negatives results. Moreover, as suggested above, the collection of four vials reduces this risk. Since it is not possible to evaluate a positivity rate per position, we verify that some positive vials were incubated in cell No. 01-A-F03, which was the case. Thus, the impact related to a defect of position No. 01-A-F03 seems very low.

Follow up

We evaluated the performance of our instrument during the following semesters. The false-positive rate was 0.17% and 0.10% in the second half of 2016 and the first one of 2017 respectively. With the exception of one position that reported two false positive vials, all false positives vials were incubated in a different position. A single vial considered as a false-positive was incubated in position No. 01-A-F03.

Discussion

We follow the preconizations of the QUAMIC, which are based on the pre-analytical, analytical and post-analytical indicators, for monitoring in continue the performance of our blood cultures instrument [1]. This strategy is more relevant than performing external and internal quality control. For the first half of 2016, the false-positive rate reaches the goal we set regarding previous reports [3-5]. Nevertheless, the prospective statement of the positions involved in the detection of false-positive vials allowed us to identify a defective one. Blood culture instruments could generate a false-positive result in case of major leukocytosis and consequently overfilled vials [2]. Considering defective position No. 01-A-F03, most of the patients display a moderate leukocytosis which would not generate a false-positive result. Nevertheless, we were unable to identify if the vials were overfilled as the blood volume was not recorded prospectively.
An undetected defective position is probably a rare event whose frequency remains to be evaluated. Its impact is low if the instructions for blood culture collection are applied (i.e. number of vials and volume of blood sampled). Otherwise, it could have a negative impact on the total volume of blood collected and consequently lead to overlooking bacteremia. Recording position of unexplained false positive reading (i.e. neither due to overfilled vials nor leukocytosis) is simple and not time-consuming if performed prospectively. It could usefully complete the analytical specificity indicator based on the false positive rate.

Conflict of interest: none of the authors has any conflict of interest to disclose.

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