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Field screening test methods: performance criteria and performance characteristics

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Abstract

Field-portable test methods may be quantitative, semi-quantitative, or qualitative and screening methods are often used in the field to determine if the concentration of a toxic substance exceeds regulatory or recommended standards or action levels. For on-site analysis, accurate quantitative tests for field measurements may not be available, depending on the analyte(s) or specific field situation. Thus, in lieu of more definitive test methods, screening tests which are based on qualitative or semi-quantitative methods are often used for making immediate decisions in the field, e.g. for compliance or risk assessment. Also, quantitative methods may be used for screening purposes in many instances. To ensure the quality of these screening tests and the decisions that are made based upon their results, screening methods need to be evaluated with sufficient data and should meet basic performance criteria prior to their being employed for decision-making purposes. Although quantitative, semi-quantitative and qualitative methods demonstrate different characteristics, it is desired that the performance criteria for all three method categories be consistent. If there is consistency, then one can have a sound basis for selecting the most appropriate test(s) for a given application. In order to unify the performance criteria for the different types of methods, a performance function is used to characterise both qualitative and semi-quantitative methods; in turn, this performance function is related to that for quantitative methods. False negative rates, false positive rates, sensitivity and specificity are key characteristics of screening methods that can be determined from the pertinent performance curves. The performance characteristics of each method are related to the uncertainty region that is associated with each method and the applicable uncertainty regions can be gleaned from the performance curves. Also, various options for using multiple test results to improve decisions based on test results are provided. Published by Elsevier Science B.V.

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1. Introduction

On-site screening tests are often used for qualitative or semi-quantitative measurement applications in the environmental and industrial hygiene fields. Screening measurements are performed in the field in order to estimate human exposures to toxic chemicals, or to estimate the content(s) of toxic chemicals in materials or on contaminated surfaces, so that elevated exposures to toxic substances can be avoided. The principal aim in conducting screening analysis may not be to quantify the level of a particular toxic chemical, but rather to determine if the chemical in question is present above or below a regulatory or recommended standard value or action level.

For toxic chemicals in ambient air within the US, the applicable regulatory standards for avoidance of excessive exposures and health effects include standards promulgated by the US Environmental Protection Agency (EPA) [1]. For toxic substances in workplace air of US workplaces, applicable standards and action levels include US Occupational Safety and Health Administration (OSHA) Permissible Exposure Levels (PELs) [2], US National Institute for Occupational Safety and Health (NIOSH) Recommended Exposure Levels (RELs) [3], or American Conference of Governmental Industrial Hygienists (ACGIH) Threshold Limit Values (TLVs) [4]. For toxic chemicals in bulk matrices and materials (such as soils and paints), the applicable standards in the US may be set by a variety of federal agencies (e.g. EPA or the US Consumer Products Safety Commission [CPSC]) so that proper precautions may be undertaken to avoid human over-exposures to toxic substances. Standards for toxic chemical surface contamination in the US have been promulgated by such agencies as EPA and the US Nuclear Regulatory Commission (NRC) in order to provide criteria to determine when surface decontamination is warranted. Apart from standards and action levels established by federal agencies and other organisations, many states have reffered regulatory standards which may be more stringent than those set by the federal government or national and international standards bodies. These represent examples of standards and action levels which are usually of interest to environmental scientists and industrial hygienists in their efforts to prevent human over-exposures to toxic chemicals in the environment and in the workplace.

Field screening tests can be either qualitative, such as chemical spot tests (e.g. [5,6]), or semi-quantitative or even quantitative, such as portable X-ray fluorescence (e.g. [6–8]) or portable anodic stripping voltammetric (e.g. [7,9]) measurements. A qualitative test consists of a screening analysis which returns either a positive result (indicating the presence of the analyte of interest) or a negative response (indicating the absence of the analyte). A quantitative method, when used for screening analysis, can be treated in a qualitative manner by converting quantitatively measured results to positives or negatives by comparison with a pre-specified threshold value. A semi-quantitative test consists of a screening analysis wherein a value is recorded which is an estimate of the concentration of analyte present in the test sample, but the confidence interval about the measured value is greater than that for a corresponding quantitative analysis.

In this paper, we describe performance functions for qualitative, semi-quantitative and quantitative analysis, so that performance criteria and performance characteristics for each type of screening test can be compared and contrasted based on a statistically rigorous formalism. By examining the performance functions of the different types of methods, it

is possible to unify the statistical treatment of performance criteria and characteristics in a manner which enables direct comparisons to be made. Once the performance characteristics and performance criteria of screening tests are estimated, potential applications of such tests for field screening measurements can be assessed.

2. Qualitative methods and performance curves

Clearly, before a method can be used in screening tests, it must be evaluated and should be found to meet certain desired performance criteria. A minimum requirement of a given test method is related to false positive and false negative rates. A test result is a false negative if a negative result is observed but the true value is above the standard value or action level. Conversely, a result is a false positive if a positive result is observed when the true value is below the threshold level. Obviously, we seek to minimise both false positive and false negative rates to the extent possible.

An ideal qualitative test method would have a zero false negative and a zero false positive rate. That is, the ideal method would be 100% sure to give a positive response when the true concentration is above the standard and 100% certain to return a negative result when the true concentration is below the threshold value. However, such performance is clearly unrealistic. A method can conceivably have either a zero false negative rate or a zero false positive rate, but it is practically impossible to demonstrate both, since, the positive or negative response rate cannot in practice be immediately changed from 0 to 100% at a single (the standard, or threshold) concentration level. Thus, an uncertainty region around the standard value should be allowed to accommodate the change in response rate with the change in analyte concentration, which is not instantaneous. Also, a qualitative method usually demonstrates a small, but non-zero, false positive and/or false negative response rate. Hence a realistic requirement for a qualitative screening method should allow for limited false negative and false positive response rates, along with a specified uncertainty region about the standard value.

It is natural that the positive response rate of a qualitative test method depends on the true concentration and it is expected that the positive response rate will increase as the true concentration increases (e.g. [10]). To statistically model the performance curve of a qualitative test, we must define several variables and functions. Let x be the true analyte concentration, c be the standard value, $P(x)$ be the positive response rate and $N(x)$ be the negative response rate of the screening method at x. A screening method can be statistically characterised by $P(x)$ and $N(x)$, called performance functions. Also, let $I(x) = 1 - P(x) - N(x)$. Then $I(x)$ is the inconclusive rate of responses at x. For a binary method (one reporting only positive or negative responses, i.e. no "inconclusive" results), $I(x) = 0$.

Given $x < c$, $P(x)$ is the false positive rate and $N(x)$ is the correct negative response rate at x. Conversely, for $x > c$, $P(x)$ is the correct positive response rate and $N(x)$ is the false negative rate at x. Given the false positive rate α_0 and the false negative rate α_1 (expressed as probabilities), we have the interval (c_0, c_1) such that the region bounded by $P(c_0) = \alpha_0$ and $N(c_1) = \alpha_1$ is the uncertainty region corresponding to false response rates. When $I(x) = 0$, (c_0, c_1) is also the uncertainty region corresponding to correct response rates: $1 - N(c_0) = \alpha_0$ and $1 - P(c_1) = \alpha_1$ (see Fig. 1). However, when $I(x) > 0$, the uncertainty

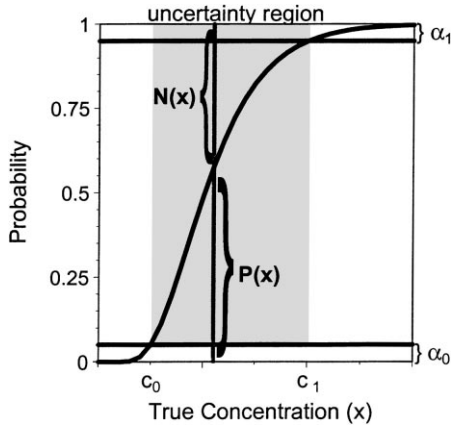

Fig. 1. Performance function and performance parameters for a binary (yes/no) qualitative test method.

region corresponding to correct response rates is different from the uncertainty region corresponding to false response rates. In this case, the uncertainty region corresponding to correct response rates is given by (d_0, d_1), where d_0 and d_1 are concentration levels and satisfy $1 - N(d_0) = \alpha_0$ and $1 - P(d_1) = \alpha_1$. The relationship between the performance functions and performance parameters for this case can be seen in Fig. 2.

To ensure the quality of qualitative screening tests, the performance criteria need to specify the uncertainty region (c_0, c_1) and the maximum false response rates allowed; alternatively, the criteria need to specify the uncertainty region (d_0, d_1) and the correct response rates required. Stated in terms of false positive and false negative rates, we have that:

(**A**) the false positive rate at or below c_0 is less than or equal to α_0, and the false negative response rate at or above c_1 is less than or equal to α_1.

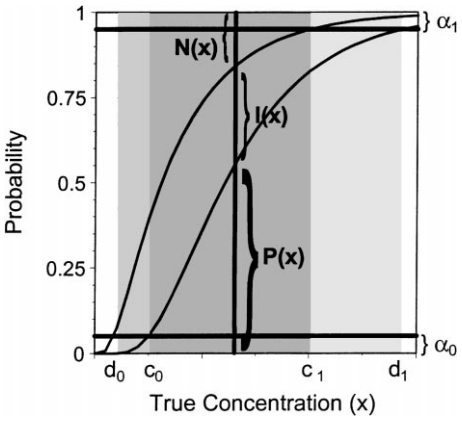

Fig. 2. Performance functions and performance parameters of a qualitative test method with inconclusive outcomes.

In terms of correct positive and correct negative response rates, we have that:

(**B**) the correct negative response rate at or below d_0 is greater than or equal to $1 - \alpha_0$, and the correct positive response rate at or above d_1 is greater than or equal to $1 - \alpha_1$.

For screening tests, the correct positive response rate is known as sensitivity and the correct negative response rate is called specificity in medically-related applications (e.g. [11]).

For screening test methods that can only report either positive or negative results, these two criteria (i.e. criteria (**A**) and (**B**) elucidated above) are identical. In this case, if the performance function $P(x)$ is a monotonically increasing function of x, then the performance criterion is equivalent to $P(c_0) < \alpha_0$ and $1 - P(c_1) < \alpha_1$. However, one test method may meet the criterion (**A**), but not the criterion (**B**). This occurs when applying a test method that can report a result as either positive, negative, or inconclusive result (see Fig. 2).

3. Semi-quantitative and quantitative screening methods

Measurement methods that return a numerical value rather than a yes/no (positive/negative) response are frequently employed for screening analysis in the field. Such screening test methods may be viewed as quantitative methods that have low precision or high bias, resulting in poorer overall accuracy than definitive quantitative methods used for fixed-site laboratory analysis. These quantitative screening methods are often referred to as semi-quantitative methods to indicate that the methods do not meet the same performance requirements for accuracy (precision and bias) as more definitive recognised quantitative methods. Of course, quantitative methods meeting more stringent performance requirements for accuracy may also be used for screening purposes. The use of semi-quantitative and/or quantitative methods for screening purposes may be manifested in the use of such methods for making decisions as to whether the measured analyte concentration is above or below the standard or action level of interest.

When a semi-quantitative or quantitative method is used in screening tests, a threshold value may be established to convert each measurement to a qualitative outcome. As a measurement method which returns a numerical value, the performance of the method is characterised by its bias and precision, or its measurement distribution. If measurements are normally distributed, the distribution of results at each concentration level is determined by its mean and standard deviation. As a qualitative test procedure, the performance function depends on the threshold value and its distribution of numerical measurements (which would be converted to positive or negative responses).

Suppose that $m(x)$ and $s(x)$ are the mean response function and the standard deviation function, respectively, of a given measurement method. Then the performance function of the derived qualitative method is given by

$$P(x) = \Phi\left\{\frac{[m(x) - t]}{s(x)}\right\}$$

here $\Phi(x)$ is the cumulative distribution function of a standard normal random variable x and t is the threshold value of the method and is usually defined as the expected response value at the standard: $t = m(c)$.

Considering the mean response function and the standard deviation function of a semi-quantitative or quantitative method, the performance function and performance parameters of this method will depend on the threshold value of interest. Given the false positive and false negative rates a_0 and a_1 (expressed as probabilities) the $(1-\alpha_0-\alpha_1)100\%$ confidence interval at x is expressed by $(L(x), U(x))$, where

$$L(x) = m(x) - z(1-\alpha_1)s(x)$$

$$U(x) = m(x) + z(1-\alpha_0)s(x)$$

and $z(1-\alpha)$ is the $(1-\alpha)100\%$ percentile of the standard normal distribution. The uncertainty region (c_0, c_1) associated with this case can be obtained by solving the following equations: $U(c_0) = t$ and $L(c_1) = t$.

If a method has a constant bias B and a constant relative standard deviation R, then

$$m(x) = (B+1)x$$

and

$$s(x) = Rm(x) = R(B+1)x$$

In this case, the uncertainty region (in terms of concentration) is given by

$$c_0 = \frac{t}{\{(1+B)[1+Rz(1-\alpha_1)]\}}$$

$$c_1 = \frac{t}{\{(1+B)[1-Rz(1-\alpha_0)]\}}$$

In applications of analytical chemistry we are usually interested in 95% confidence, so we choose $\alpha = 0.05$. For a method with no bias, $B = 0$ and with $\alpha_0 = \alpha_1 = 0.05$, we have

$$c_0 = \frac{t}{(1+1.645R)}$$

and

$$c_1 = \frac{t}{(1-1.645R)}$$

A semi-quantitative or quantitative method can also be characterised by its overall accuracy, which is denoted by A. For a quantitative method meeting the desired accuracy criterion as defined by the US National Institute for Occupational Safety and Health (NIOSH), 95% of measurements fall in the $\pm A\%$ of the true concentration level [12]. Other accuracy criteria could be used, of course, but we have chosen for this example the criterion for accuracy which is used most often in the occupational hygiene field. Accuracy as defined here is a function of precision and bias. A simple approximation of the function relating accuracy to precision and bias is given by

$$A = |B| + 1.96R$$

A quantitative method is recommended for use by NIOSH if $A < 0.25$; that is, at least 95% of the measurements must fall within $\pm 25\%$ of the true value. For our purposes here we

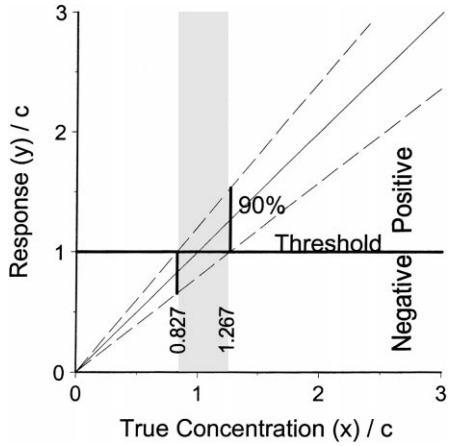

Fig. 3. A quantitative method with $A = 0.25$ and converted to a qualitative outcomes (positive or negative with respect to a threshold level) by use of a threshold value.

desire to use a quantitative method for screening purposes. Considering an ideal situation with $A < 0.25$ and $B = 0$, we have that $c_0 = 0.827t$ and $c_1 = 1.267t$. In the case where $B = 0$ and $t = m(c) = c$, then $c_0 = 0.827c$ and $c_1 = 1.267c$ (see Fig. 3).

A semi-quantitative method with poor precision or high bias may meet the criterion (**A**) previously described by reporting results as inconclusive in order to reduce its false negative and false positive rates. For an extreme example, consider a method giving 100% inconclusive results. This method has a 0% false negative and a 0% false positive rate; however, this method also has a 0% correct positive rate and a 0% correct negative rate. Such a (hypothetical) method is obviously useless since it provides no information about the sample concentration and cannot be used for decision-making purposes.

A method with a non-zero inconclusive rate can be characterised by its positive response rate function $P(x)$ and its negative response rate function $N(x)$. Recall that the inconclusive response rate is given by $I(x) = 1 - P(x) - N(x)$. For methods with inconclusive ranges, there are two types of uncertainty region intervals: (c_0, c_1) corresponding to the false positive and false negative rates and (d_0, d_1) corresponding to the correct positive and correct negative response rates (see Fig. 2). If $I(x) = 0$ for all x, then $c_0 = d_0$ and $c_1 = d_1$.

If a quantitative (or semi-quantitative) method does not meet the performance criterion (**B**) by defining a threshold t, the method can conceivably meet the criterion (**A**) by our defining an inconclusive range (t_0, t_1) such that $t_0 = L(c_1)$ and $t_1 = U(c_0)$ (see Fig. 4). In this case, $P(x)$ is the probability that a measurement at x is greater than t_1, $N(x)$ is the probability that a measurement at x is less than t_0 and $I(x)$ is the probability that a measurement at x falls in the interval (t_0, t_1). In this manner, defining an inconclusive range would allow a semi-quantitative method to be used for screening analysis. The width of the inconclusive range will obviously depend on the accuracy of the semi-quantitative method.

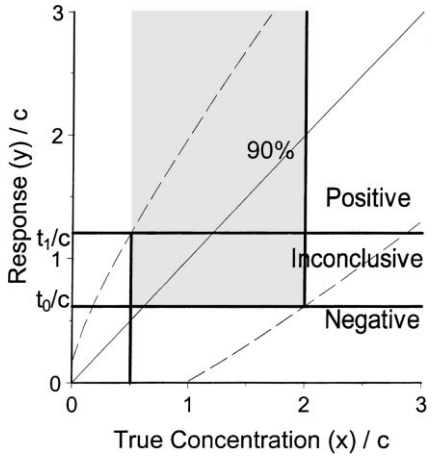

Fig. 4. A semi-quantitative method converted to qualitative results (positive or negative) with inconclusive outcomes.

4. Decisions based on multiple readings

If reporting results based on a single reading, a qualitative method does not offer the advantage of reducing its false response rates. However, if multiple readings can be used to arrive at a conclusion, a qualitative method can be used to meet the performance criterion (**A**). For example, consider a method with $P(c_0) > \alpha_0$ or $N(c_1) > \alpha_1$ that does not meet the criterion (**A**). We select n readings such that $[P(c_0)]^n < \alpha_0$ and $[N(c_1)]^n < \alpha_1$. Then this method meets the criterion (**A**) by our reporting a positive result if all n readings are positive, and by reporting a negative result if all n readings are negative, and by reporting an inclusive result otherwise. In using this strategy, false negative and false positive rates are reduced, but the sensitivity and specificity are reduced also. Refer to Table 1, wherein $\alpha_0 = P(c_0)$, $\alpha_1 = P(c_1)$, $\beta_0 = N(c_0)$, and $\beta_1 = N(c_1)$.

There are two other ways to arrive at conclusions based on multiple readings. For one, multiple readings can be used in parallel, whereby a positive result is reported if any one of the successive readings is positive and a negative result is reported if all of the readings are negative. In this instance, the sensitivity is increased and the false negative rate is decreased. However, the specificity is decreased and the false positive rate is increased.

Table 1
Probabilities of negative, positive and inconclusive responses at x (the true concentration)

	$x = c_0$	$x = c_1$
Negative (all negative responses)	$(1-\beta_0)^n$	${\alpha_1}^n$
Positive (all positive responses)	${\alpha_0}^n$	$(1-\beta_1)^n$
Inconclusive (otherwise)	$1-\alpha_0^n-(1-\beta_0)^n$	$1-\alpha_1^n-(1-\beta_1)^n$

An example where this approach could be useful would be the use of qualitative spot test kits for the testing of painted surfaces, where the kits were designed to have low false negative rates but higher incidences of false positive results [13]. Alternatively, multiple readings can be used in series, whereby a positive result is reported if all readings are positive, and a negative result is reported if at least one reading is negative. Multiple readings used in series have the opposite effects on each performance parameter compared to multiple readings used in parallel. That is, in such a case the specificity is increased and the false positive rate is decreased, while the sensitivity is decreased while the false negative rate is increased.

5. Classification of methods

As mentioned earlier, a screening method can be characterised by its performance function. The uncertainty region associated with a given method represents the accuracy of the method and defines an interval around the standard value where the method cannot determine (to a high probability) compliance or non-compliance with the standard (or conclusions regarding concentrations above or below the threshold level). The smaller the uncertainty interval, the more accurate the method. Based on the width of the uncertainty region, screening methods can be classified into two groups.

(**I**) Quantitatively equivalent: Methods meet the criterion (**B**) with $\alpha_0 = \alpha_1 = 0.05$; $d_0 = 0.827c$ and $d_1 = 1.267c$.

(**II**) Semi-quantitatively equivalent: Methods not in group (**I**) but meet the criterion (**B**) with $\alpha_0 = \alpha_1 = 0.05$; $d_0 = 0.5c$ and $d_1 = 2c$ (for example).

Thus, methods with uncertainty regions contained within the interval $(0.827c, 1.267c)$ are class (**I**) methods. The class (**I**) method definition is similar to the classification scheme currently used in the industrial hygiene field by NIOSH and OSHA (see [12]). For a quantitative method to be recognised as a class (**I**) method, its precision (relative standard deviation, R) must be less than 0.128. If the bias cannot be adjusted by adjusting the threshold value, then R for the method must be less than

$$\min\left\{\frac{[1(0.827(1+B))-1]}{[z(1-\alpha_1)]}, \frac{[1-1(1.267(1+B))]}{[z(1-\alpha_0)]}\right\}$$

The relationship between overall accuracy as a function of precision and bias is described fully in [12].

Class (**II**) methods have uncertainty regions not contained in the interval $(0.827c, 1.267c)$, but rather demonstrate a wider interval, (e.g. $c/2$, $2c$). As an example, the class (**II**) method definition is the classification scheme currently used by the EPA to classify field screening X-ray fluorescence measurements for lead in paint [14]. A semi-quantitative method with constant $R < 0.365$ can be a class (**II**) method if the threshold value is properly selected according to method bias. If the threshold value is set to the standard value: $t = c$, then R must be less than

$$\min\left\{\frac{[1(0.5(1+B))-1]}{[z(1-\alpha_1)]}, \frac{[1-1(2(1+B))]}{[z(1-\alpha_0)]}\right\}$$

For a quantitative method, if the 5th percentile of its measurement distribution at $d_1 = 2c$ is greater than the 95th percentile of its measurement distribution at $d_0 = c/2$, then this method is at least a class (**II**) method. For this method to be converted to a qualitative method, the threshold value can be any number between these two percentiles.

6. Discussion

It is desirable that a screening test method be both highly sensitive and highly specific, with a very small uncertainty region about the applicable standard value for the hazardous substance(s) in question. However, this is often impossible since the uncertainty region for a given method is related to the sensitivity and specificity of the method. Setting a smaller uncertainty region results in lower sensitivity and specificity, so there is generally a trade-off between minimising the uncertainty interval and maximising the correct response rates (sensitivity and specificity). Due to this relationship, a method can be evaluated in one of the following ways: (a) evaluate method sensitivity and specificity for a specified uncertainty region or (b) estimate the uncertainty region with a given sensitivity and specificity.

There is also generally a trade-off between the sensitivity and specificity of a given test method. This trade-off has to do with the cut-off between positive and negative results. For a given method and for our purposes described here, the cut-off is related to the threshold value. Because of this trade-off, a method can increase its chance of having positive responses (i.e. the method is made more sensitive) at the expense of an increased chance of having false positive responses (i.e. the method is made less specific). Thus, a method could be very sensitive but not specific, or vice-versa.

One way of addressing the problem of the trade-off between sensitivity and specificity is to use the results of several screening tests together, with these tests performed either in parallel or in series. Tests in parallel would give a positive result if any one of multiple test responses is positive. In this case, sensitivity is increased compared to that of each individual test. Tests conducted in series would give a positive result if all test results for multiple measurements are positive. Because a series of all positive results is more likely to represent a true positive conclusion, tests in series serve to increase method specificity.

Clearly the use of semi-quantitative and quantitative methods for screening purposes may depend on the intended application or purpose of the measurement. The discussion here has focused on the use of such measurements for making decisions concerning analyte concentrations above or below a given standard or action level (threshold). The statistical treatment presented in this paper can be applied to virtually any method which returns a numerical value for any analyte of interest and therefore has general applicability to field screening analysis.

In conclusion, a statistical treatment has been presented which allows for the examination of performance criteria and performance characteristics of field screening test methods. By implementing the statistical treatments presented here on screening measurement data with subsequent confirmatory analysis, it is possible to evaluate qualitative, semi-quantitative, and quantitative field methods for their utility in screening analysis for a given analyte of interest. It should therefore, be possible to use the results from screening analysis to make defensible decisions concerning potential human exposures to toxic chemicals.

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