differentiation between bacterial and viral infections. Often the diagnostic value of CRP is found superior to that of the erythrocyte sedimentation rate (ESR) and superior or equal to that of the white blood cell count (WBC). The disadvantage of this point of care testing is the long detection time. These tests need between minimum 30 minutes and 2 hours.

[0009] Clinically, it can be challenging to differentiate certain systemic viral and bacterial infections. Bacterial cultures are usually performed in cases of severe infection such as pneumonia, or when the consequence of missing a diagnosis can lead to severe complications, such as with Strep throat. Often, cultures are difficult to obtain. Unfortunately, viral cultures are not routinely performed due to the significant time delay in receiving results. New viral screening PCR panels are useful, but they are expensive and do not provide information at the point of care, because the results can only be achieved after 24 hours. Thus, there remains a need for a simple, easy to use diagnostic test that is capable of differentiating viral and bacterial infections in short time!

[0010] WO2010/033963 discloses a lateral flow immunoassay for detection and differentiation between viral and bacterial infections. The bacterial marker is CRP and the viral marker is Mx-A-protein. The assay is marketed in Europe under the tradename FebriDx®. However, according to a study FebriDx® has only an accuracy of 63% and 84% for identifying bacterial and viral infections respectively[17]. Therefore, there is still the need for a rapid point of care diagnostic assay for more accurate and reliable discrimination between bacterial and viral infections in patients.

Summary

[0010a] In one aspect, the present disclosure refers to a point-of-care (POC) assay device comprising

a. a sample application zone, and
b. a detection zone with a first detection reagent with binding affinity to Mx-B-protein (Mx-B), and a second detection reagent with binding affinity to C-reactive Protein or procalcitonin (CRP/PCT), and
c. wherein the device is configured to detect Mx-B and CRP/PCT in a sample from a subject to discriminate between bacterial and viral infection.

[0010b] In another aspect, the present disclosure refers to a method for discriminating

between bacterial and viral infection in a subject, comprising the steps of

a. providing a sample obtained from said subject,
b. providing the test system disclosed herein,
c. applying the sample to the test system,
d. observing the absence or presence of the detectable reagent-marker complex to determine whether the sample contains Mx-B and/or CRP and/or PCT, and wherein
e. the presence of Mx-B and the absence and/or low detection of CRP/PCT is indicative for a viral infection,
f. the absence of Mx-B and the presence of CRP/PCT is indicative for a bacterial infection;
g. the presence of Mx-B and the presence of CRP/PCT is indicative for a mixed infection; and
h. thereby determining the infection status of the patient.

[0011] It is the object of the present disclosure to provide an improved and more accurate and specific diagnostic assay for reliable discrimination of bacterial and viral infections in patients in short time. The object is solved by the subject matter of the present disclosure.

[0012] According to the present disclosure, there is provided a point-of-care (POC) immune assay device comprising:

a. a sample application zone, and
b. a detection zone with a first detection reagent with binding affinity to Mx-B-protein (Mx-B), and a second detection reagent with binding affinity to C-reactive Protein (CRP/PCT), and

wherein the device is configured to detect Mx-B and CRP/PCT in a sample from a subject to discriminate between bacterial and viral infection.

[0013] According to a further example of the present disclosure, there is provided a point-of-care (POC) immune assay device comprising:

a. a sample application zone, and
b. a detection zone with a first detection reagent with binding affinity to Mx-B-protein (Mx-B), and a second detection reagent with binding affinity to C-reactive Protein (CRP), and a third detection reagent with binding affinity to procalcitonin (PCT) and/or fourth detection reagent with binding affinity to bactericidal/permeability-increasing protein BPI, and

wherein the device is configured to detect Mx-B and CRP/PCT in a sample from a subject to discriminate between bacterial and viral infection.

[0014] One example of the present disclosure relates to the device as described herein, further comprising a third detection reagent with binding affinity to BPI.

[0015] One example of the present disclosure relates to device of as described herein, wherein said detection reagents are selected from synthetic molecules, nucleotides, nucleic acids, aptamers, peptides, proteins, enzymes, and antibodies.

[0016] One example of the present disclosure relates to the device as described herein, wherein said detection reagents are labelled with a detectable marker.

[0017] A further example of the present disclosure relates to device as described herein, wherein the detectable marker is selected from an enzyme label, fluorescent label, radiolabel, particulate label, colored latex particle, colored plastic particle, a colored phosphor particle, and a fluorescent particle.

[0018] A further example of the present disclosure relates to the device as described herein, further comprising a test window configured to allow observation of the test results.

[0019] A further example of the present disclosure relates to the device as described herein, wherein the detection reagents are chemically conjugated to the detectable marker to form a permanent, irreversible reagent-marker complex.

[0020] A further example of the present disclosure relates to the as described herein, wherein the detectable marker conjugated to the detection reagent is configured to be visible to a user when the sample is positive for Mx-B and/or CRP and/or PCT and/or BPI and.

[0021] A further example of the present disclosure relates to the device as described herein, wherein the device is configured to/or PCT and/or BPI in human blood samples.

[0022] One example of the present disclosure relates to a method for discriminating between bacterial and viral infection in a subject, comprising the steps of:

a. providing a sample from said subject,
b. providing the test system as described herein,
c. applying the sample to the test system,
d. observing the absence or presence of the detectable reagent-marker complex to determine whether the sample contains Mx-B and/or CRP and/or PCT and/or BPI, and
e. determining the infection status of the patient.

[0023] One example of the present disclosure relates to the method as described herein, wherein

a. the presence of Mx-B and the absence and/or low detection of CRP/PCT/BPI is indicative for a viral infection,
b. the absence of Mx-B and the presence of CRP/PCT/BPI is indicative for a bacterial infection; and
c. the presence of Mx-B and the presence of CRP/PCT/BPI is indicative for a mixed infection.

[0024] A further example of the present disclosure relates to the method as described herein, further observing the absence or presence of the detectable reagent-marker complex to determine whether the sample contains CRP/PCT/BPI.

[0025] One example of the present disclosure relates to the method as described herein, wherein

a. the presence of Mx-B and the absence of CRP/PCT and BPI is indicative for a viral infection,
b. the absence of Mx-B and the presence of CRP/PCT and BPI is indicative for a bacterial infection; and
c. the presence of Mx-B and the presence of CRP/PCT and BPI is indicative for a mixed infection.

[0026] A further example of the present disclosure relates to the method as described herein, wherein the sample is a blood sample.

[0027] A further example of the present disclosure relates to the method as described herein, wherein the presence of Mx-B, CRP/PCT and/or BPI is visible to the naked eye.

Brief description of drawings

[0028] Fig. 1A depicts an exemplary test stet up consisting of three test strips coated with labelled antibodies.

[0029] Fig. 1B depicts the different test pictures for viral infections, bacterial infection, mixed infections, or doubtful infection.

[0030] Fig. 2 shows the results for different viral and bacterial pathogens.

Description of Embodiments

[0031] The present invention provides a point of care assay that is capable of differentiating viral and bacterial infections in short time. Specifically, there is provided a point of care diagnostic device comprising test markers for both viral and bacterial infection which effectively assists the medical doctor in the rapid differentiation of viral and bacterial infections. The point of care assay has the following advantages:

1.) This assay may dramatically reduce health care costs by limiting misdiagnosis and consequently over- and misuse of antibiotics.

2) The efficacy and ensurement of this assay is that the resistance against antibiotics will be reduced, because the antibiotics will be used only when a bacterial infection is present.

3) This assay will increase the diagnostic portfolio of doctor’s office and pharmacists.

[0032] Thus, the present invention contributes use antibiotics appropriately. This means using antibiotics only when needed and, if needed, using them correctly.

[0033] Antibiotics do not fight infections caused by viruses like colds, flu, most sore throats, and bronchitis. Even many sinus and ear infections can get better without antibiotics. Instead, symptom relief might be the best treatment option for these infections. Taking antibiotics for viral infections, such as colds, flu, most sore throats, and bronchitis:

- will not cure the infection;
- will not keep other people from getting sick;
- will not help you or your child feel better;
- may cause unnecessary and harmful side effects; and

Claims

1. A point-of-care (POC) assay device comprising
   a. a sample application zone, and
   b. a detection zone with a first detection reagent with binding affinity to Mx-B-protein (Mx-B), and a second detection reagent with binding affinity to C-reactive Protein or procalcitonin (CRP/PCT), and
   c. wherein the device is configured to detect Mx-B and CRP/PCT in a sample from a subject to discriminate between bacterial and viral infection.
2. The device of claim 1, further comprising a third detection reagent with binding affinity to BPI.
3. The device of claim 1 or 2, wherein said detection reagents are selected from synthetic molecules, nucleotides, nucleic acids, aptamers, peptides, proteins, enzymes, and antibodies.
4. The device of claim 3, wherein said detection reagents are labelled with a detectable marker.
5. The device of claim 4, wherein the detectable marker is selected from an enzyme label, fluorescent label, radiolabel, particulate label, colored latex particle, colored plastic particle, a colored phosphor particle, and a fluorescent particle.
6. The device of any one of claims 1 to 5, further comprising a test window configured to allow observation of the test results.
7. The device of any one of claims 4 to 6, wherein the detection reagents are chemically conjugated to the detectable marker to form a permanent, irreversible reagent-marker complex.
8. The device of any one of claims 4 to 7, wherein the detectable marker conjugated to the detection reagent is configured to be visible to a user when the sample is positive for Mx-B and/or CRP and/or PCT and/or BPI.
9. The device of any one of claims 1 to 8, wherein the device is configured to qualitatively and/or quantitatively measure the presence of Mx-B and/or CRP and/or PCT in human blood samples.
10. A method for discriminating between bacterial and viral infection in a subject, comprising the steps of
    a. providing a sample obtained from said subject,
    b. providing the test system of any one of claims 1 to 9,

c. applying the sample to the test system,
d. observing the absence or presence of the detectable reagent-marker complex to determine whether the sample contains Mx-B and/or CRP and/or PCT, and wherein
e. the presence of Mx-B and the absence and/or low detection of CRP/PCT is indicative for a viral infection,
f. the absence of Mx-B and the presence of CRP/PCT is indicative for a bacterial infection;
g. the presence of Mx-B and the presence of CRP/PCT is indicative for a mixed infection; and
h. thereby determining the infection status of the patient.

11. The method of claim 10, further observing the absence or presence of the detectable reagent-marker complex to determine whether the sample contains BPI.
12. The method of claim 11, wherein
    a. the presence of Mx-B and the absence of CRP/PCT and BPI is indicative for a viral infection,
    b. the absence of Mx-B and the presence of CRP/PCT and BPI is indicative for a bacterial infection; and
    c. the presence of Mx-B and the presence of CRP/PCT and BPI is indicative for a mixed infection.
13. The method of any one of claims 10 to 12, wherein the sample is a blood sample.
14. The method of any one of claims 10 to 13, wherein the presence of Mx-B, and/or CRP/PCT is visible to the naked eye.