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(54) Title: DETECTION, IDENTIFICATION AND DIFFERENTIATION OF PROTEUS SPECIES USING THE SPACER REGION

(57) Abstract: The present invention relates to new nucleic acid sequences derived from the ITS region, between the 16S and 23S ribosomal ribonucleic acid (rRNA) or rRNA genes, to be used for the specific detection and/or identification of *Proteus* species, in particular of *Proteus mirabilis*, *Proteus vulgaris* and/or *Proteus penneri*, in a biological sample. The present invention relates also to a method for the specific detection and/or identification of *Proteus* species, in particular *Proteus mirabilis*, *Proteus vulgaris* and/or *Proteus penneri*, using said new nucleic acid sequences derived from the ITS (Internal Transcribed Spacer) region. It relates also to nucleic acid primers to be used for the amplification of said spacer region of *Proteus* species in a sample.



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INTERNATIONAL SEARCH REPORT

International Application No

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A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 C12Q1/68

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 C12Q

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ, BIOSIS, MEDLINE, EMBASE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 03/095677 A (KEUM KI-CHANG ;MEDIGENES (KR); YOO NAE-CHOON (KR); YOO SEUNG-MIN () 20 November 2003 (2003-11-20) page 2 page 3 - page 6; table 1 -----	1-3,5-17
X	WO 00/52203 A (ANTHONY RICHARD MICHAEL ;BROWN TIMOTHY JAMES (GB); KING S COLLEGE) 8 September 2000 (2000-09-08) page 2 page 4 - page 5 -----	1-3,5-17
A	US 6 512 105 B1 (MCDONOUGH SHERROL HOFFA ET AL) 28 January 2003 (2003-01-28) example 16; table 48 ----- -/--	

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search

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INTERNATIONAL SEARCH REPORT

International Application No
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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 00/66785 A (GEN PROBE INC ;HOGAN JAMES J (US); GORDON PATRICIA (US)) 9 November 2000 (2000-11-09) page 12; claims 15,31 -----	
A	US 6 025 132 A (VAN HEUVERSWYN HUGO ET AL) 15 February 2000 (2000-02-15) column 1; claims 1,32 column 2 column 11 -----	

INTERNATIONAL SEARCH REPORT

International application No.
PCT/EP2005/050464

Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

1-3, 5-17 (all partially)

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

Invention 1: claims 1-3, 5-17 (all partially)

An isolated nucleic acid molecule consisting of SEQ ID NO: 1, a nucleic acid molecule that hybridizes to said molecule for the detection and/or identification of Proteus species, a nucleic acid molecule that hybridizes to said molecule for the detection and/or identification of Proteus species with the proviso that the nucleic acid molecule ATACGTGTTATGTGC is excluded, a set of two and a set of three polynucleotide probes that hybridize to molecule with SEQ ID NO: 1, a composition comprising one of said molecules, the use of said molecule with SEQ ID NO: 1 as a probe and as a primer, the use of said nucleic acid molecule and said primers and probes for the detection and/or identification of Proteus species in a hybridization and/or amplification method, a method for detecting or identifying Proteus species using SEQ ID NO: 1 and a kit for the detection and/or identification of Proteus species comprising SEQ ID NO: 1.

Inventions 2 to 17: claims 1-3, 5-17 (all partially)

Inventions 2 to 17, as invention 1, wherein the nucleic acid molecule consist of SEQ ID NO: 2 to 17, respectively.

Invention 18: claims 4, 7-17 (all partially)

An isolated nucleic acid molecule selected from the group consisting of SEQ ID NO: 21 to 24 and 37 to 39, a composition comprising any of said molecules, use of any of said nucleic acid molecules as a probe, use of any of said nucleic acid molecules as a primer, use of any of nucleic acid molecules with SEQ ID NO: 21 to 24 and any of nucleic acid molecules with SEQ ID NO: 37 to 39 for the detection and/or identification of Proteus species in a hybridization and/or amplification method, a method for detecting or identifying Proteus species using at least of nucleic acid sequence with SEQ ID NO: 21 to 24 and 37 to 39, and a kit for the detection and/or identification of Proteus species comprising at least one of the nucleic acid sequences with SEQ ID NO: 21 to 24 and 37 to 39.

Inventions 19 to 22: claims 4, 7-17 (all partially)

Inventions 19 to 22, as invention 18, wherein the nucleic acid molecules consist of the following groups: SEQ ID NO: 25, 26, 40 and 41 (for invention 19), SEQ ID NO: 27 to 29 and 42 (for invention 20), SEQ ID NO: 30, 31, 43 and 44 (for invention 21) and SEQ ID NO: 32, 33, 45 and 46 (for invention 22).

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Invention 23: claims 4, 7-17 (all partially)

An isolated nucleic acid molecule consisting of SEQ ID NO: 18, a composition comprising said molecule, use of any of said molecule as a probe, use of said molecule as a primer, use of said molecule for the detection and/or identification of Proteus species in a hybridization and/or amplification method, a method for detecting or identifying Proteus species using nucleic acid sequence with SEQ ID NO: 18, and a kit for the detection and/or identification of Proteus species comprising nucleic acid sequence with SEQ ID NO: 18.

Inventions 24 to 49: claims 4, 7-17 (all partially)

Inventions 24 to 49, as invention 23, wherein the nucleic acid molecule consist of SEQ ID NO: 19, 20, 34, 35, 36, 47 to 67, respectively.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/EP2005/050464

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