US00D989861S

(12) United States Design Patent

Dobak, III et al.

(10) Patent No.: US D989,861 S
(45) Date of Patent: ** Jun. 20, 2023

(54) **DERMATOLOGY REPORT DOCUMENT**

(71) Applicant: **DermTech, Inc.**, La Jolla, CA (US)

(72) Inventors: **John Daniel Dobak, III**, La Jolla, CA (US); **Sarah Dion**, San Diego, CA (US); **Burkhard Jansen**, La Jolla, CA (US); **Jane Bue**, Vista, CA (US)

(73) Assignee: **DERMTECH, INC.**, San Diego, CA (US)

(**) Term: **15 Years**

(21) Appl. No.: **29/770,783**

(22) Filed: **Feb. 16, 2021**

(51) **LOC (14) Cl.** **19-01**

(52) **U.S. Cl.**
USPC **D19/1**

(58) **Field of Classification Search**
USPC D19/1–12, 20–34; 40/124.01–124.15, 40/672, 661, 726, 776, 617, 633; 229/72, 229/92, 92.1, 299.01; 206/449; D21/385; D20/10, 22, 40, 27, 42, 11; D14/435–437; D24/231; 705/2–3
CPC .. B42D 15/042; B42D 15/022; B42D 15/045; B42D 15/027; B42D 25/00; B42D 25/20; B42D 25/23; B42D 25/26; B42D 25/29; B42D 25/30; B42D 25/285; B42D 2033/00; B42D 2033/04; B42D 2033/08; B42D 2033/10; B42D 2033/16; B42D 2033/18; B42D 2033/20; B42D 2033/22; B42D 2033/28; B42D 2033/30; B65D 27/00; B65D 27/04
See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

4,122,947 A 10/1978 Falla
5,190,049 A 3/1993 Briggs et al.
5,921,396 A 7/1999 Brown, Jr.
D424,541 S 5/2000 Mugura
D430,120 S 8/2000 Yasui et al.
6,106,732 A 8/2000 Johnston et al.
6,176,836 B1 1/2001 Trudil et al.
(Continued)

FOREIGN PATENT DOCUMENTS

WO WO-0010579 A1 3/2000
WO WO-03001985 A2 1/2003
(Continued)

OTHER PUBLICATIONS

Co-pending U.S. Appl. No. 29/770,784, inventors Dobak; John et al., filed on Feb. 16, 2021.
(Continued)

Primary Examiner — Abraham Bahta
(74) *Attorney, Agent, or Firm* — Wilson Sonsini Goodrich & Rosati

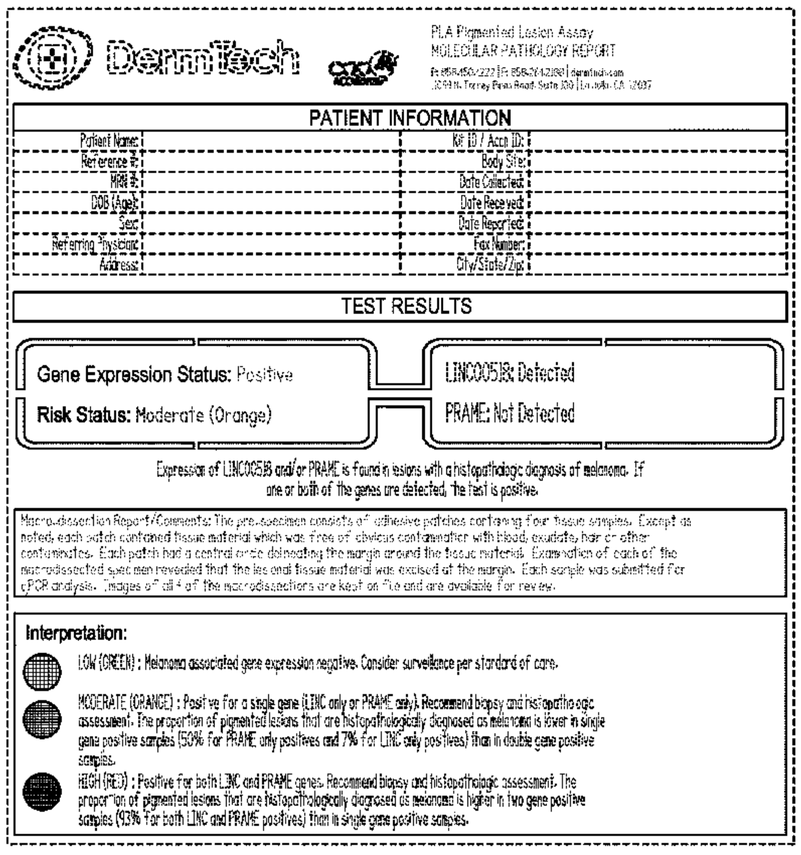
(57) **CLAIM**

The ornamental design for a dermatology report document, as shown and described.

DESCRIPTION

The sole FIGURE is a front view of a dermatology report document, showing our new design.
The peripheral broken lines represent an unclaimed boundary of the dermatology report document and form no part of the claimed design. Within the peripheral broken lines, the broken line showing of text and other features of the dermatology report document is for environmental purposes only and forms no part of the claimed design. The difference in crosshatch shading indicates a contrast of appearance and does not depict any particular color, texture, or material.
The dermatology report document has no appreciable thickness.

1 Claim, 1 Drawing Sheet



(56) **References Cited**

U.S. PATENT DOCUMENTS

6,447,463	B1	9/2002	Borkowski	
6,720,145	B2	4/2004	Rheins et al.	
D504,440	S	4/2005	Luquet	
6,949,338	B2	9/2005	Rheins et al.	
7,183,057	B2	2/2007	Benson	
7,297,480	B2	11/2007	Vogt	
D570,857	S	6/2008	Nguyen et al.	
7,921,999	B1	4/2011	Kimball	
7,989,165	B2	8/2011	Benson	
D673,166	S	12/2012	Mori et al.	
8,541,170	B2	9/2013	Kennedy et al.	
8,938,684	B2	1/2015	Guertler et al.	
9,057,109	B2	6/2015	Chang	
D764,580	S *	8/2016	Solomon	D19/1
D764,581	S *	8/2016	Solomon	D19/1
D786,282	S	5/2017	Donnelly	
D788,142	S	5/2017	Burke	
D816,697	S	5/2018	Ledford et al.	
D816,699	S	5/2018	Ledford et al.	
D816,700	S	5/2018	Bayer et al.	
D824,402	S	7/2018	Donnelly	
D847,840	S	5/2019	Poschel et al.	
10,407,729	B2	9/2019	Chang	
D865,056	S *	10/2019	Martin	D19/1
D874,474	S	2/2020	Rognlie et al.	
10,709,428	B2	7/2020	Palmer et al.	
D900,130	S	10/2020	Matos et al.	
D930,010	S	9/2021	Caudill et al.	
D944,284	S	2/2022	Metzger et al.	
D944,286	S	2/2022	Sanchez et al.	
D946,017	S	3/2022	Courtney et al.	
11,307,876	B1	4/2022	Leonard et al.	
2002/0110824	A1	8/2002	Rheins et al.	
2002/0115086	A1	8/2002	Rheins et al.	
2002/0119471	A1	8/2002	Rheins et al.	
2002/0127573	A1	9/2002	Rheins et al.	
2002/0150918	A1	10/2002	Rheins et al.	
2003/0045810	A1	3/2003	Borkowski	
2003/0098580	A1	5/2003	Christy	
2006/0242554	A1	10/2006	Gerace et al.	
2007/0087323	A1	4/2007	Armitage et al.	
2007/0243537	A1	10/2007	Tuck et al.	
2007/0281314	A1	12/2007	Benson	
2008/0138819	A1	6/2008	Vogt	
2008/0200870	A1	8/2008	Palmroos et al.	
2008/0274908	A1	11/2008	Chang	
2010/0086501	A1	4/2010	Chang et al.	
2010/0105102	A1	4/2010	Hanes et al.	
2010/0279877	A1	11/2010	Vogt	
2011/0160080	A1	6/2011	Chang	
2012/0065086	A1	3/2012	Benson	
2013/0296185	A1	11/2013	Benson	
2014/0154684	A1	6/2014	Chang	
2014/0323331	A1	10/2014	Chang et al.	
2015/0005184	A1	1/2015	Alsobrook et al.	
2015/0259739	A1	9/2015	Chang et al.	
2015/0361500	A1	12/2015	Ang et al.	
2016/0024595	A1	1/2016	Alsobrook, II	
2019/0367994	A1	12/2019	Chang	
2020/0149115	A1	5/2020	Dobak et al.	
2020/0289099	A1	9/2020	Palmer et al.	
2020/0308649	A1	10/2020	Dobak et al.	
2020/0308657	A1	10/2020	Dobak et al.	
2020/0319205	A1	10/2020	Dobak et al.	
2020/0383665	A1	12/2020	Palmer et al.	
2020/0407800	A1	12/2020	Dobak et al.	
2021/0196247	A1	7/2021	Palmer et al.	
2021/0198749	A1	7/2021	Chang	
2021/0222246	A1	7/2021	Dobak et al.	
2021/0222247	A1	7/2021	Dobak et al.	
2021/0222258	A1	7/2021	Chang	
2021/0246514	A1	8/2021	Chang	

FOREIGN PATENT DOCUMENTS

WO	WO-2005100603	A2	10/2005
WO	WO-2007124072	A2	11/2007
WO	WO-2008137772	A1	11/2008
WO	WO-2009140550	A2	11/2009
WO	WO-2010025341	A2	3/2010
WO	WO-2010097773	A1	9/2010
WO	WO-2014176446	A1	10/2014
WO	WO-2014210467	A1	12/2014
WO	WO-2016014705	A1	1/2016
WO	WO-2016179043	A1	11/2016
WO	WO-2017165199	A1	9/2017
WO	WO-2018191268	A1	10/2018
WO	WO-2019161126	A1	8/2019
WO	WO-2019183620	A1	9/2019
WO	WO-2019217478	A1	11/2019
WO	WO-2020008192	A2	1/2020
WO	WO-2020198229	A1	10/2020
WO	WO-2020206085	A1	10/2020
WO	WO-2022221326	A1	10/2022

OTHER PUBLICATIONS

Co-pending U.S. Appl. No. 29/770,785, inventors Dobak; John et al., filed on Feb. 16, 2021.

Co-pending U.S. Appl. No. 29/770,786, inventors Dobak; John et al., filed on Feb. 16, 2021.

Co-pending U.S. Appl. No. 29/796,477, inventor Dobak; John, filed on Jun. 24, 2021.

Co-pending U.S. Appl. No. 17/933,336, inventors Dubridge; Robert B. et al., filed Sep. 19, 2022.

Co-pending U.S. Appl. No. 29/866,396, inventor Makris; Gina, filed Sep. 9, 2022.

Co-pending U.S. Appl. No. 29/866,397, inventor Makris; Gina, filed Sep. 9, 2022.

Co-pending U.S. Appl. No. 29/866,398, inventor Makris; Gina, filed Sep. 9, 2022.

Co-pending U.S. Appl. No. 29/866,399, inventor Makris; Gina, filed Sep. 9, 2022.

U.S. Appl. No. 17/195,541 Office Action dated Sep. 28, 2022.

Cerda et al. Geometry and Physics of Wrinkling. Phys Rev Lett 90(7):074302 (2003).

Childs. Noninvasive gene expression testing in amelanotic melanoma. JAMA Dermatol 154(2):223-224(2018).

Co-pending U.S. Appl. No. 29/770,784, inventors Dobak; John et al., filed Feb. 16, 2021.

Co-pending U.S. Appl. No. 29/770,785, inventors Dobak; John et al., filed Feb. 16, 2021.

Co-pending U.S. Appl. No. 29/770,786, inventors Dobak; John et al., filed Feb. 16, 2021.

Co-pending U.S. Appl. No. 29/796,477, inventor Dobak; John, filed Jun. 24, 2021.

Dalbe et al. Multiscale Stick-Slip Dynamics of Adhesive Tape Peeling. Phys Rev Lett 115(12):128301 (2015).

De Zotti et al. Bending to Kinetic Energy Transfer in Adhesive Peel Front Microinstability. Phys Rev Lett 122(6):068005 (2019).

Ferris et al. Impact on clinical practice of a non-invasive gene expression melanoma rule-out test: 12-month follow-up of negative test results and utility data from a large US registry study. Dermatology Online J 25(5):pii (May 2019).

Ferris et al. Noninvasive analysis of high-risk driver mutations and gene expression profiles in primary cutaneous melanoma. J Invest Dermatol 139:1127-1134 (2019).

Ferris et al. Real-world performance and utility of a noninvasive gene expression assay to evaluate melanoma risk in pigmented lesions. Melanoma Res 28(5):478-482 (2018).

Ferris et al. Utility of a noninvasive 2-gene molecular assay for cutaneous melanoma and effect on the decision to biopsy. JAMA Dermatol 153(7):675-680 (2017).

Gerami et al. Development and validation of a noninvasive 2-gene molecular assay for cutaneous melanoma. J Am Acad Dermatol 76(1):114-120.e2 (2017).

(56) **References Cited**

OTHER PUBLICATIONS

Hornberger et al. Clinical and economic implications of a noninvasive molecular pathology assay for early detection of melanoma. JAMA Dermatol 154(9):1-8 (2018).
Instructions for use DermTech adhesive skin biopsy kit. DermTech. Available at http://dermtech.com/wp-content/uploads/2015/10/dermtech-ifu-skin-collection-v7.pdf (Revised data Oct. 2015) (1 pg.).
Itoh et al. Generation of 3D skin equivalents fully reconstituted from human induced pluripotent stem cells (iPSCs). PLoS One 8(10):e77673 (2013).
Jansen et al. Gene expression analysis differentiates melanomas from Spitz nevi. J Drugs Dermatol 17(5):574-576 (2018).
Liu et al. Inhibition of p38 MAPK signaling augments skin tumorigenesis via NOX2 driven ROS generation. PLoS One 9(5):e97245 (2014).
Neagu et al. miRNAs in the Diagnosis and Prognosis of Skin Cancer. Front Cell Dev Biol 8:71 (2020).
PCT/US2016/30287 International Search Report and Written Opinion dated Aug. 16, 2016.
Rivers et al. Non-invasive gene expression testing to rule out melanoma. Skin Therapy Letter 23(5):1-4(2018).
Rivers et al. Ruling out Melanoma: A practical guide to improving performance through non-invasive gene expression testing. Skin Therapy Letter: Family Practice Edition 14(1):4-6 (2019).
Shen et al., Epigenetic and genetic dissections of UV-induced global gene dysregulation in skin cells through multi-omics analyses. Scientific Reports 7:42646 (2017).
Shen et al., Transcriptome analysis identifies the dysregulation of ultraviolet target genes in human skin cancers. PLoS One 11(9):e0163054 [1-14] (2016).
Siegel et al. Further consideration of the pigmented lesion assay-reply. JAMA Dermatol 155(3):393-394 (2019).
Thoroddsen et al. Stick-slip substructure in rapid tape peeling. Phys Rev Lett 82(4 Pt 2):046107 (2010).
Torres et al. MicroRNA Ratios Distinguish Melanomas from Nevi. J Invest Dermatol. 140(1):164-173.e7 (2020).
Wachsman et al. Differentiation of melanoma from dysplastic nevi in suspicious pigmented skin lesions by non-invasive tape stripping. Journal of Dermatology 127(Supp 1s):S145 (2007).
Yao et al. An adhesive patch-based skin biopsy device for molecular diagnostics and skin microbiome studies. J Drugs Dermatol 16:979-986 (2017).
Yao et al. Analytical Characteristics of a Noninvasive Gene Expression Assay for Pigmented Skin Lesions. Assay Drug Del Technol 14(6):355-363 (2016).

* cited by examiner

DermTech

PLA Pigmented Lesion Assay
MOLECULAR PATHOLOGY REPORT

P: 858.450.4222 | F: 858.2642188 | dermtech.com
3099 N. Torrey Pines Road, Suite 100 | La Jolla, CA 92037

PATIENT INFORMATION

Patient Name:		Kit ID / Accn ID:	
Reference #:		Body Site:	
MRN #:		Date Collected:	
DOB (Age):		Date Received:	
Sex:		Date Reported:	
Referring Physician:		Fax Number:	
Address:		City/State/Zip:	

TEST RESULTS

Gene Expression Status: Positive

Risk Status: Moderate (Orange)

LINC00518: Detected

PRAME: Not Detected

Expression of LINC00518 and/or PRAME is found in lesions with a histopathologic diagnosis of melanoma. If one or both of the genes are detected, the test is positive.

Macro-dissection Report/Comments: The pre-specimen consists of adhesive patches containing four tissue samples. Except as noted, each patch contained tissue material which was free of obvious contamination with blood, exudate, hair or other contaminates. Each patch had a central circle delineating the margin around the tissue material. Examination of each of the macrodissected specimen revealed that the lesional tissue material was excised at the margin. Each sample was submitted for qPCR analysis. Images of all 4 of the macrodissections are kept on file and are available for review.

Interpretation:

LOW (GREEN) : Melanoma associated gene expression negative. Consider surveillance per standard of care.

MODERATE (ORANGE) : Positive for a single gene (LINC only or PRAME only). Recommend biopsy and histopathologic assessment. The proportion of pigmented lesions that are histopathologically diagnosed as melanoma is lower in single gene positive samples (50% for PRAME only positives and 7% for LINC only positives) than in double gene positive samples.

HIGH (RED) : Positive for both LINC and PRAME genes. Recommend biopsy and histopathologic assessment. The proportion of pigmented lesions that are histopathologically diagnosed as melanoma is higher in two gene positive samples (93% for both LINC and PRAME positives) than in single gene positive samples.